

PSJ17 Exh 10

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FENTORA Strategic Marketing Plan 2007

- Pain Overview
- Market Assessment
 - Market Analysis
 - Customer Analysis
 - Competitive Analysis
 - Environmental Trends
- Franchise Assessment
- Product Overview
- SWOT Analysis
- Strategy Formation
- Critical Success Factors
- Key Messages
- Implementation
- Tactical Plan
- Results Required
- Control and Monitoring



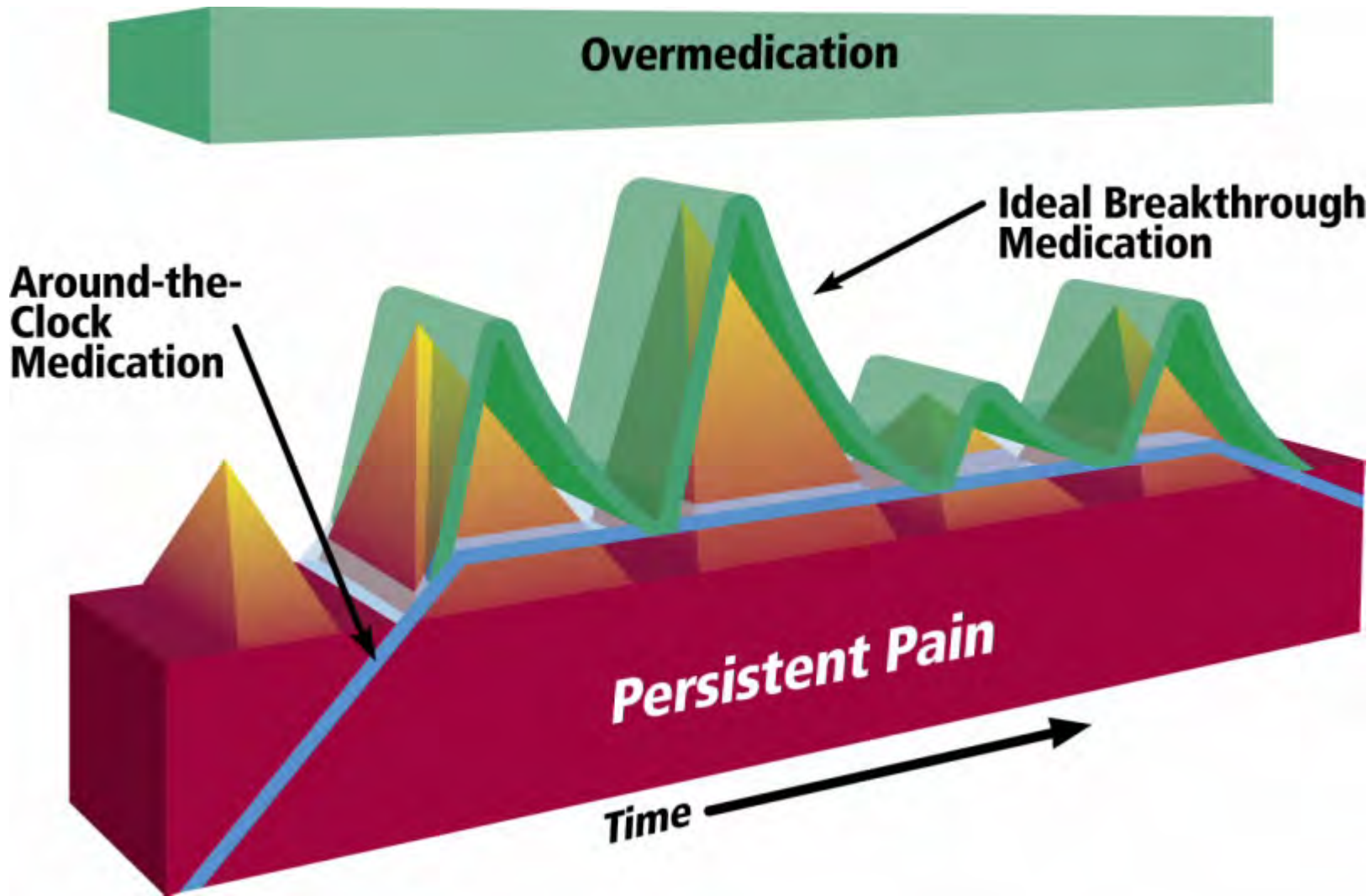
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- Market Assessment
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- **Pain is pain¹:**
 - Cancer and noncancer patients – Pathophysiology the same regardless of etiology/underlying disease
- **Chronic Pain Definition²:**
 - Chronic pain is pain that lasts beyond the expected time of healing of an injury or insult (>3 months)
- **Chronic pain often has 2 components²:**
 - **Persistent pain:**
 - Baseline pain that is continuous throughout the day
 - **Breakthrough pain (BTP)²:**
 - Transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients with otherwise stable persistent pain

1. Turk D. *Clin J Pain* 2002;18(2):75-6. 2. Portenoy RK, Hagen NA. *Pain*. 1990;41:273-281.

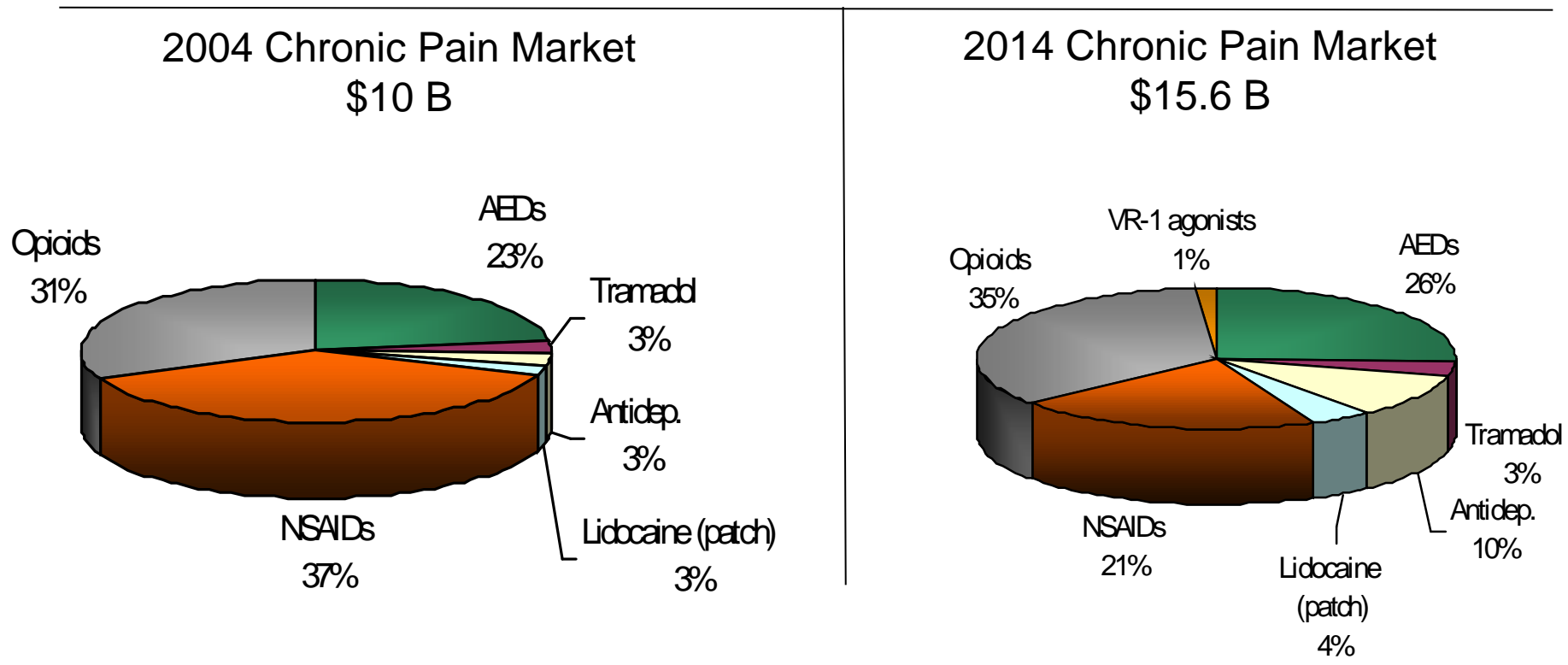
	Cancer BTP (N =63) ¹	Noncancer BTP (N=228) ⁴
Prevalence	64% to 89% ^{1,2}	74%
Median Episodes/Day	4 to 7 ¹⁻³	2
Time to Peak Intensity	43% in 3 min	50% in 5 min
Median Duration	30 min	60 min
Incident Related	55%	92%
Pathophysiology	<ul style="list-style-type: none"> •somatic (33%) •visceral (20%) •neuropathic (27%) •mixed (20%) 	<ul style="list-style-type: none"> •somatic (38%) •visceral (4%) •neuropathic (18%) •mixed (40%)

1. Portenoy, Hagen. *Pain*. 1990;41:273-281. 2. Zeppetella. *J Pain Symptom Manage*. 2000;20:87-92. 3. Portenoy et al. *Pain*. 1999;81:129-134. 4. Portenoy, et al. APS. 2005.



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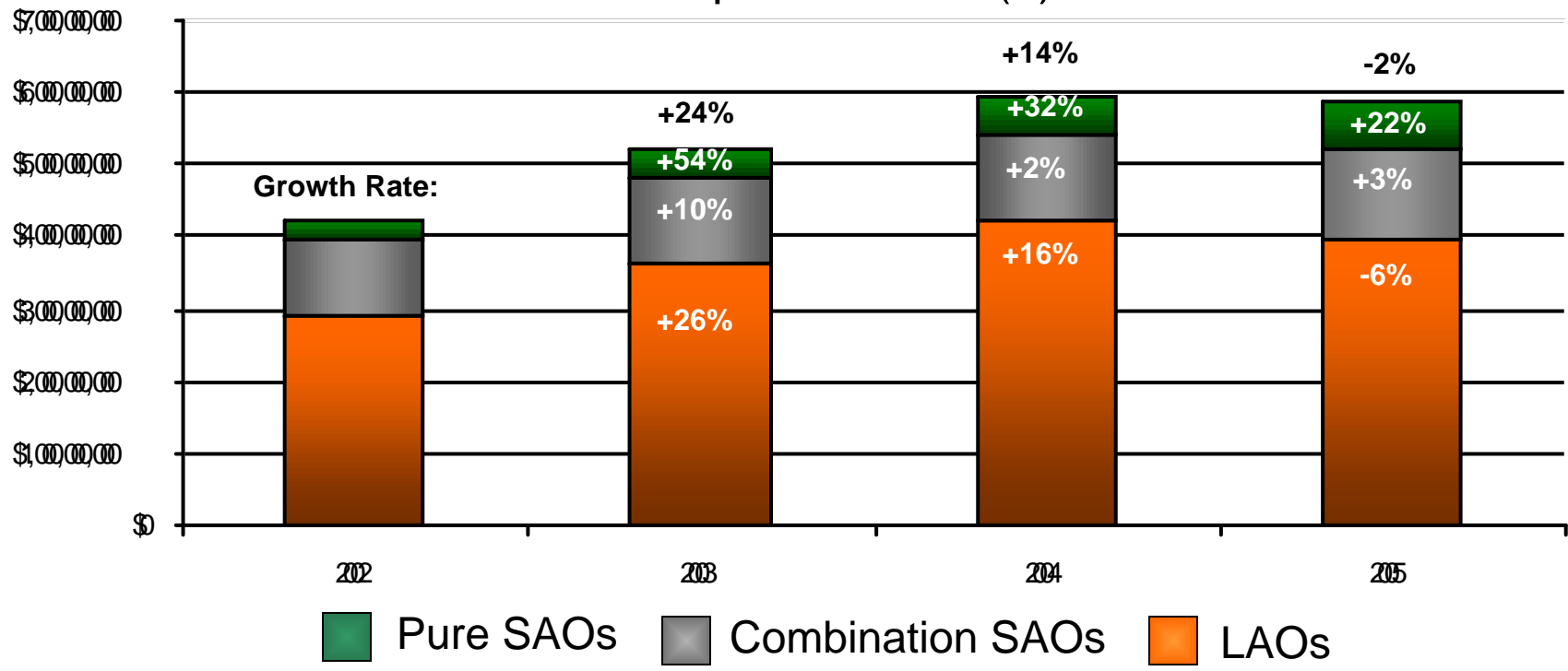
Market Shares of Leading Drugs/Drug Classes for Chronic Pain



Additional major pain states include postoperative pain and acute pain

- **Long-acting opioids (LAOs)**
 - Opioid + drug delivery technology
- **Short-acting opioids (SAOs)**
 - Combination SAO = opioid + APAP or NSAID
 - Pure SAO = opioid only
- **Rapid-onset opioids (ROOs)**
 - Onset of analgesia 15 minutes
 - ACTIQ & FENTORA considered ROOs
 - ROO concept
 - Gaining momentum (referred to in press)
 - Not fully recognized by pain community
 - Current USP definitions based on duration of action

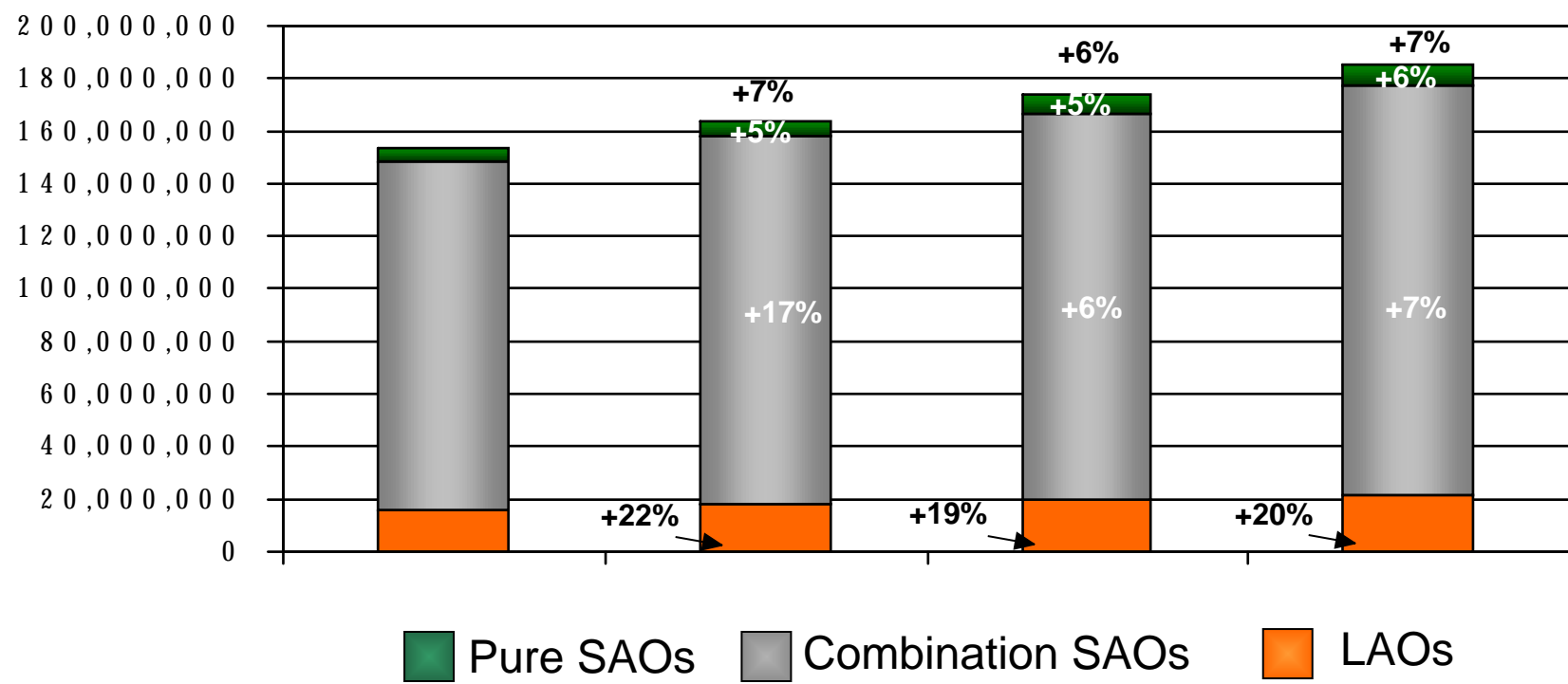
US Opioid Market (\$)



	2002	2003	2004	2005
Pure SAOs	\$ 264,801,493	\$ 410,695,554	\$ 543,595,747	\$ 662,603,120
Combination SAOs	\$ 1,056,329,808	\$ 1,166,532,565	\$ 1,189,958,330	\$ 1,220,703,479
LAOs	\$ 2,912,479,212	\$ 3,663,271,003	\$ 4,234,655,198	\$ 3,964,843,057
Totals	\$ 4,233,610,513	\$ 5,240,499,122	\$ 5,968,209,275	\$ 5,848,149,656

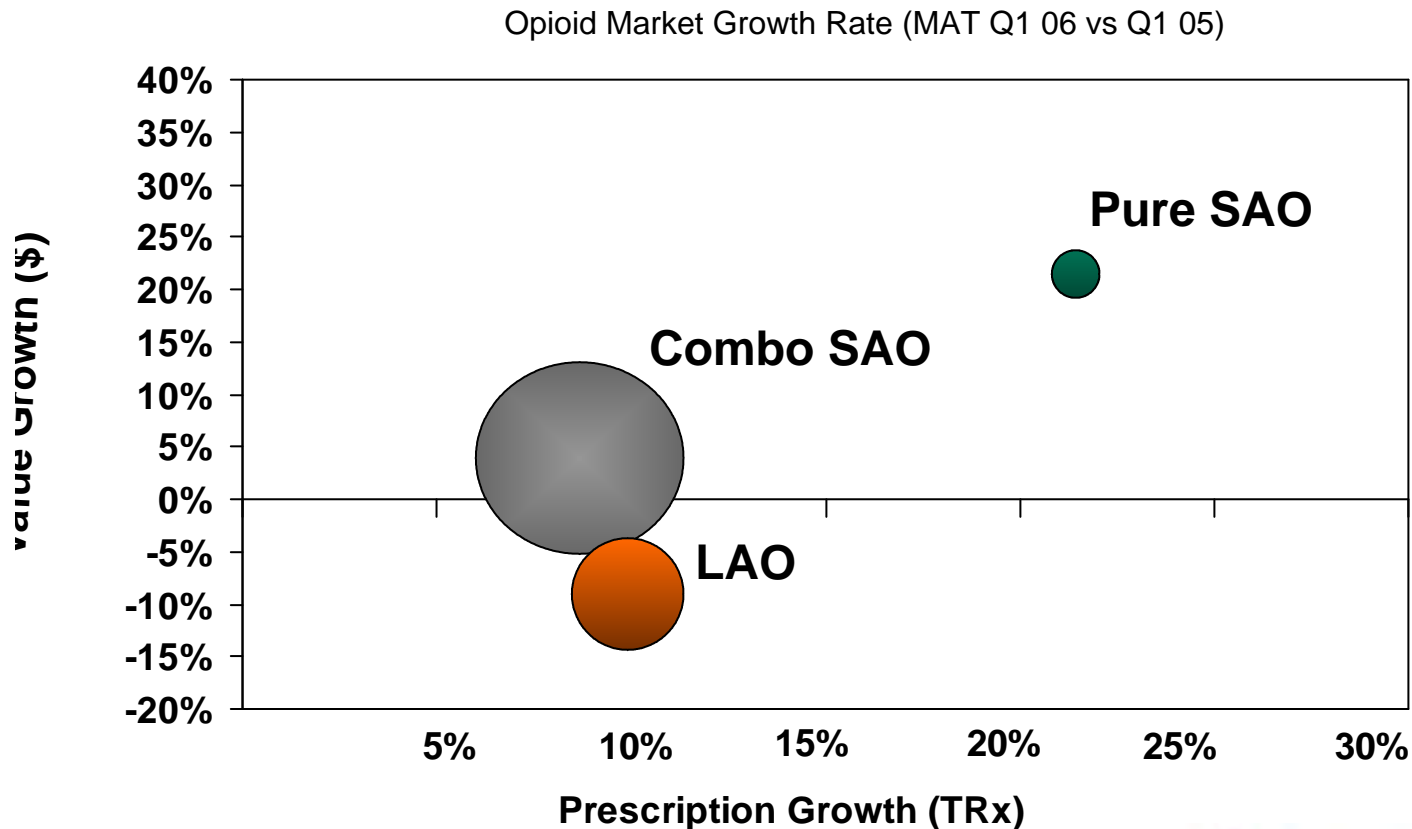


US Opioid Market (TRXs)



	2002	2003	2004	2005
Pure SAOs	4,831,199	5,872,471	6,971,310	8,352,400
Combination SAOs	132,743,549	139,794,637	146,738,836	155,644,025
LAOs	15,713,144	18,311,865	20,081,947	21,540,519
Totals	153,287,892	163,978,973	173,792,093	185,536,944

All Opioid TRx Markets Growing Total TRx Market Growing at 7%
Pure SAO market continues robust growth

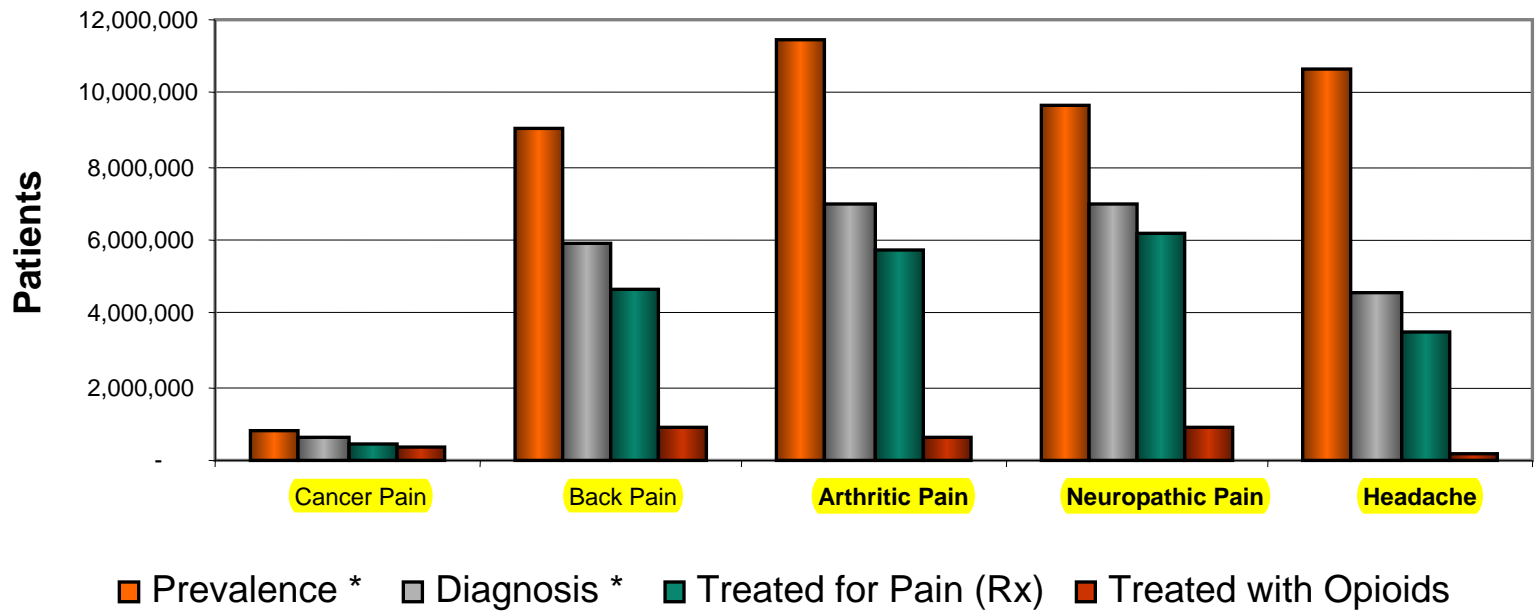


Size of bubble = TRx volume



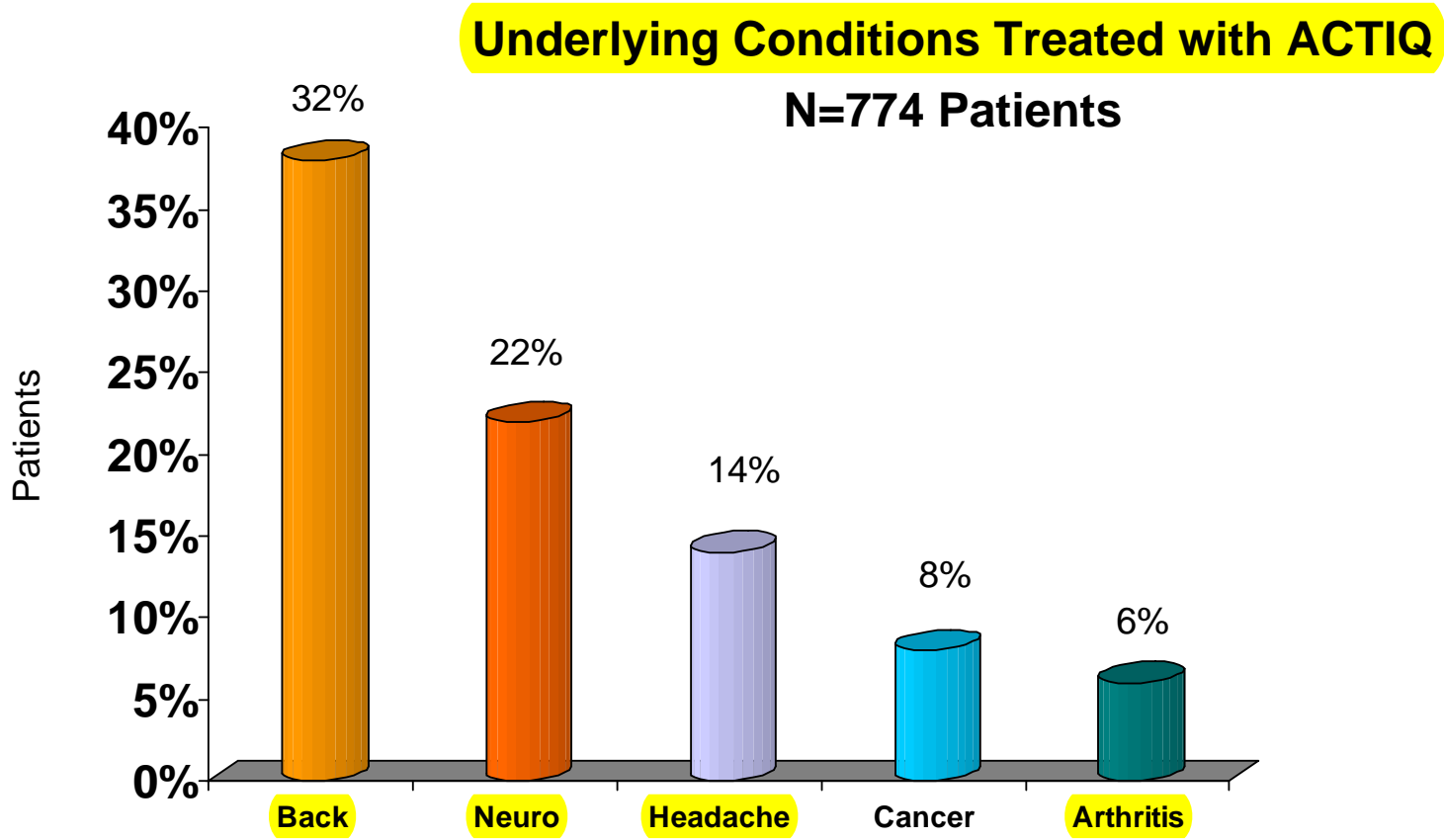
Chronic Pain market has significant potential due to high prevalence

Chronic Pain Prevalence, Diagnosis and Treatment



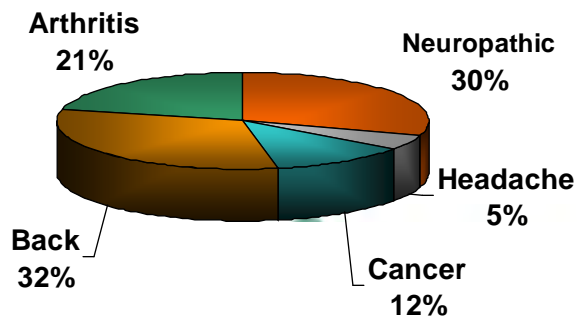
Source: Analysis of secondary data reports by Cephalon Market Research Department





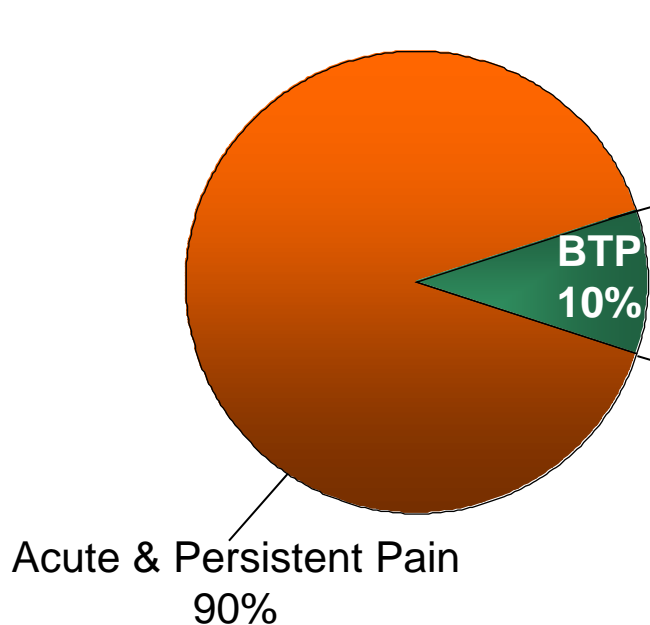
Chronic Pain Patients Treated with opioids

Estimate – 2.8 M Patients

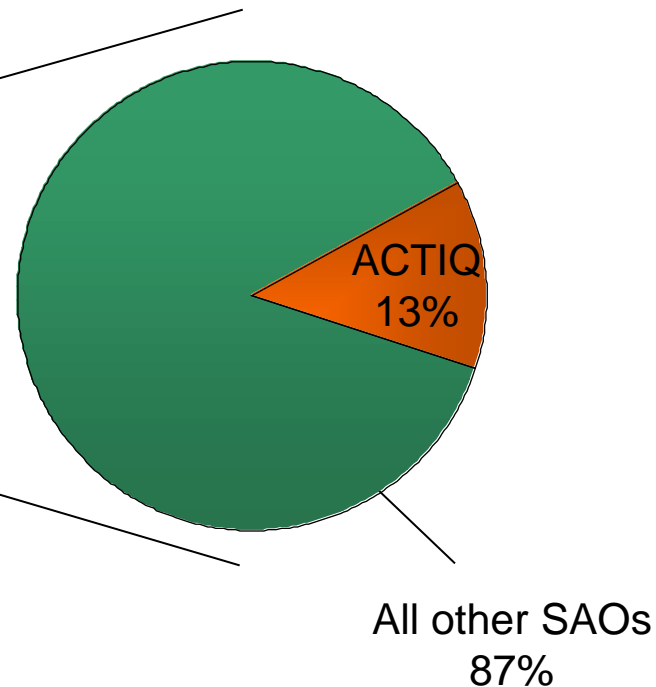


ACTIQ has not fully penetrated the market

What are SAOs used to treat?



What is used to treat BTP?



- BTP treatment small part of SAO use

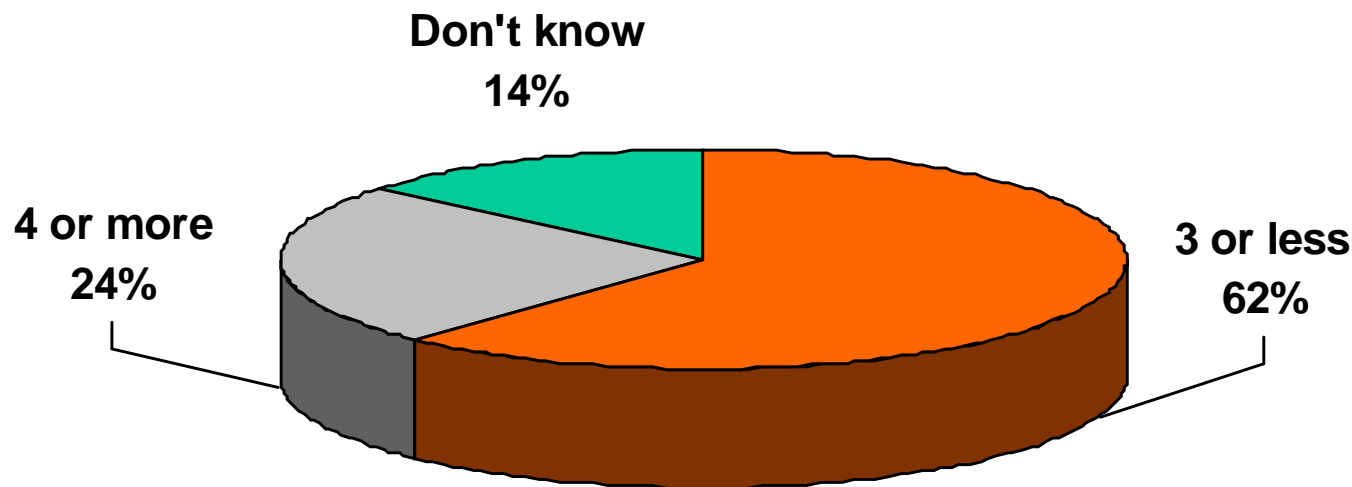
- BTP predominantly treated with other SAOs

Typical Course of Action	# of BTP episodes	
	3	4
Increase dose of LAO	34%	64%
Increase frequency of LAO	7%	12%
Increase frequency of SAO	21%	10%
Switch the LAO	2%	7%
Increase dose of SAO	28%	4%
Switch the SAO	3%	2%

- The most common treatment choice is to increase the dose of LAOs, which is a major barrier to FENTORA usage
- ACTIQ usage is most likely followed by an SAO failure



BTP Episodes Per Day (Physician Perception)



- Majority of patients (62%) have 3 episodes/day
- Quarter (24%) of patients have 4 or more episodes per day
- Over 1 in 10 physician (14%) do not know how many episodes of BTP their patients experience

Awareness for ACTIQ as a treatment for BTP is currently tied in 4th with Percocet

Short Acting Opioids	1st mention	2nd mention	3rd mention	All mentions
Hydrocodone (Lorcet, Lortab, Norco, Vicodin, Vicoprofen)	30%	25%	19%	74%
SA Oxycodone (OxyIR, Oxyfast, Roxicodone)	22%	28%	7%	57%
SA Morphine (MSIR, Roxanol)	7%	13%	25%	45%
Fentanyl (ACTIQ)	16%	8%	19%	43%
Percocet (hydrocodone + acetaminophen)	16%	16%	4%	36%
SA Hydromorphone (Dilaudid)	1%	5%	11%	16%
Tramadol (Ultracet, Ultram)	4%	2%	5%	11%
SA Propoxyphene (Balacet, Darvon, Darvocet)	0%	2%	4%	6%
SA Codeine (Tylenol #3)	1%	1%	2%	4%

Q8. For treating BTP, what are your top 3 short acting opioid choices (SAOs)??

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Combo SAO Market Share (TRx)

Key Drivers

Prescribers	2004	2005	2006 YTD
PAIN/ANESTH	4%	4%	4%
PCP	41%	41%	40%
OTHER SPEC	51%	51%	51%
NEURO	3%	3%	3%
ONCOLOGY	1%	1%	1%
PSYCH	.4%	.4%	.4%

Class of Trade	2004	2005	2006 YTD
Chain	51%	50%	51%
Independent	20%	21%	21%
Food Stores	12%	12%	12%
Long-term care	4%	4%	4%
Federal facilities	3%	3%	2%
Hospitals	3%	3%	3%
Clinics	3%	3%	3%
Other	4%	4%	5%

- PCPs and Other Specialists are the key audiences in the Combo SAO market accounting for the majority (92%) of scripts
 - Pain specialists play a lesser role in the Combo SAO market (vs ACTIQ or Pure SAOs)
-
- The SAO segment is primarily a retail-based market and a strong office-based presence is required
 - Long-term care, Hospitals and Clinics have less relative usage in the Combo SAO market (vs Pure SAO)

Source: IMS Prescribers - NPA TRx
Class of Trade – NSP Units



Pure SAO Market Share (TRx)

Prescribers	2004	2005	2006
Pain Specialists	19%	18%	18%
PCP	39%	40%	40%
OTHER SPEC	28%	30%	30%
NEURO	4%	3%	3%
ONCOLOGY	9%	8%	7%
PSYCH	1%	1%	1%

Class of Trade

Chain	37%	38%	39%
Independent	24%	24%	24%
Food Stores	10%	10%	10%
Long-term care	8%	8%	8%
Federal facilities	7%	7%	7%
Hospitals	6%	6%	6%
Clinics	5%	5%	4%
Other	4%	4%	3%

Key Drivers

- PCPs, other specialists and pain specialists account for the majority of volume
- Pain specialists are early adopters for emerging therapies and influence usage patterns
- Mainly a retail-based market requiring a strong office-based presence
- The long-term care (8%) and Pain Clinics (5%) may represent an expanded opportunity for FENTORA
- Hospital market (5%) has potential to drive new patient starts

Source: IMS Prescribers - NPA TRx
Class of Trade – NSP Units



ACTIQ Market Share (TRx)

Key Drivers

Prescribers	2004	2005	2006 (YTD)
PAIN/ANESTH	45.2%	42.9%	43.2%
PCP	25.6%	26.9%	27.0%
OTHER SPEC	15.7%	16.8%	17.3%
NEURO	7.7%	7.3%	7.0%
ONCOLOGY	3.0%	3.0%	2.8%
PSYCH	2.9%	3.0%	2.7%

Reimbursement	2004	2005
Third Party Payers (TPP)	82%	83%
Medicaid	7%	9%
Cash	11%	8%

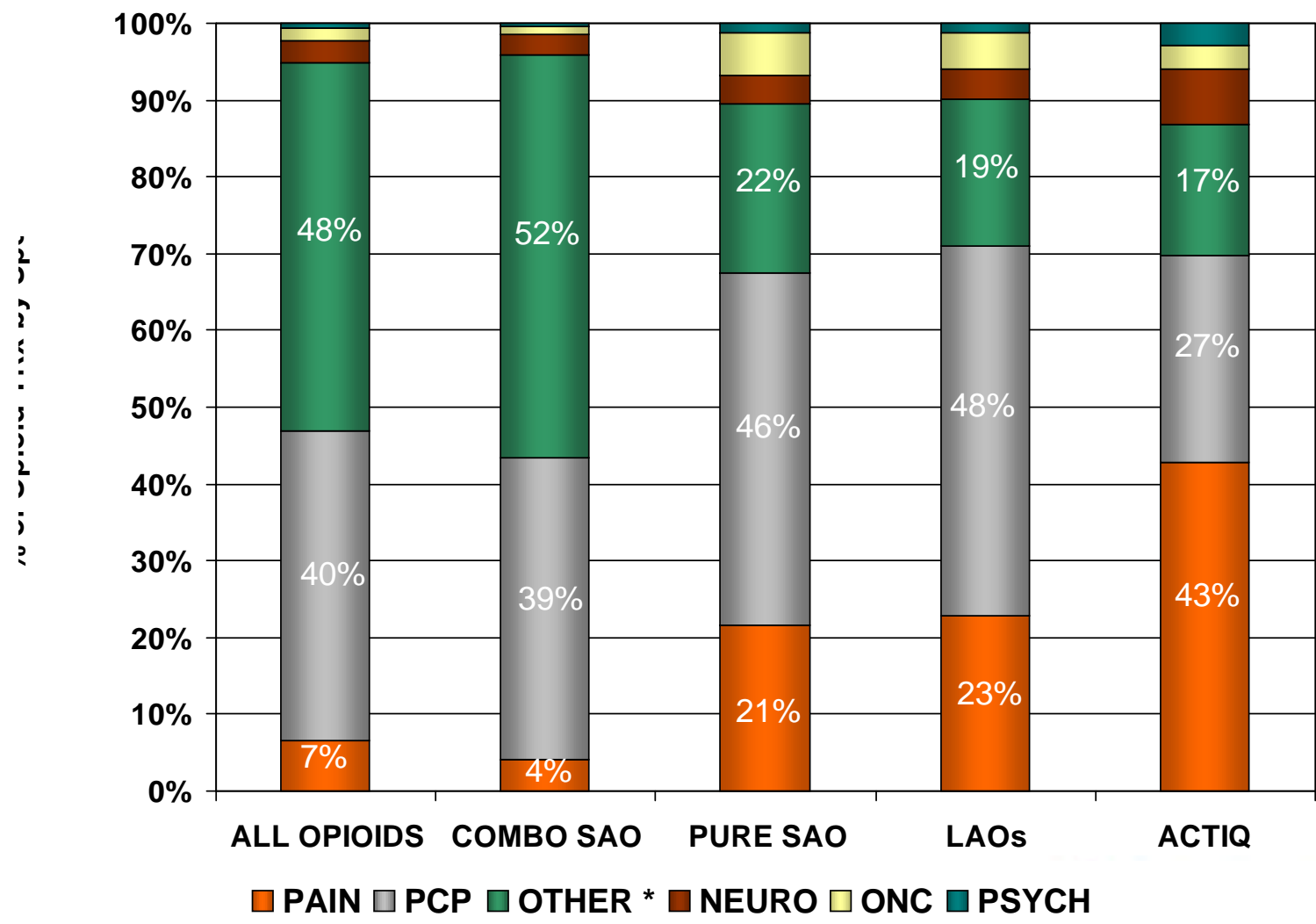
Class of Trade			
Chain	37%	38%	39%
Independent	37%	36%	35%
Food Stores	12%	12%	12%
Long-term care	4%	4%	4%
Hospitals	2%	2%	2%
Clinics	3%	3%	3%
Other	6%	6%	6%

- Pain specialists drive the largest share of ACTIQ TRxs
- PCPs represent the second largest segment and highest volume potential for FENTORA
- TPPs are the key audience in this segment and will use co-pays and prior authorization requirements to drive business to generic OTFC and SAOs
- Currently, Cephalon has limited presence in the long-term care channel, clinics and hospitals

Source: IMS Prescribers - NPA TRx
Class of Trade – NSP Units

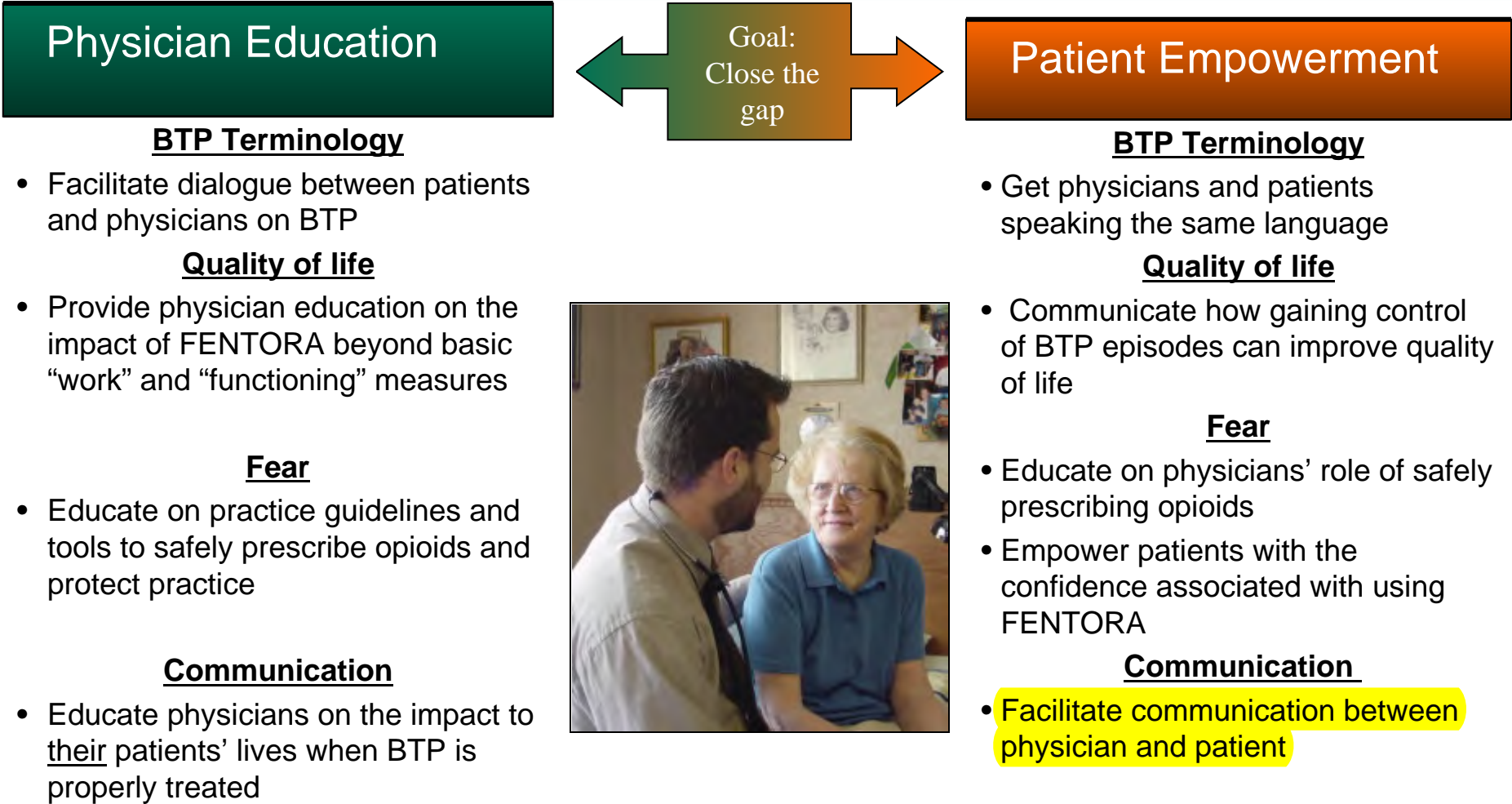
Specialty Market Share for Opioids (2005)

ACTIQ has firmly established itself with pain specialists

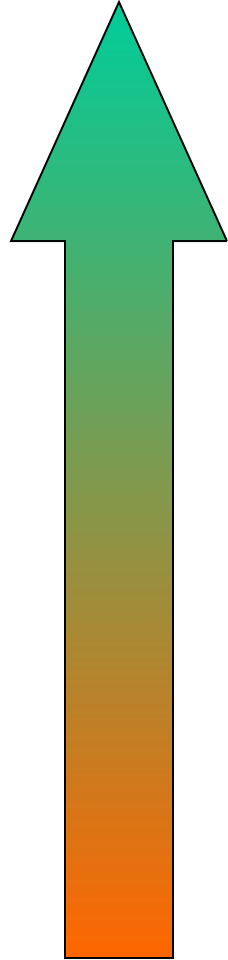


Breakthrough Pain Customer Analysis

Objectives	Methodology	Findings
Identify BTP: <ul style="list-style-type: none">• Attitudinal issues• Emotional drivers	Psychographic in-depth interviews: <ul style="list-style-type: none">• Physicians (n=27)• Patients (n=29)	Key perceptual points: <ul style="list-style-type: none">• BTP terminology• Quality of life• Fear• Communicating pain



Engaged Physician



1. **Active Expert:** These docs are highly engaged with their patients and with resolving their pain problems. They don't run from opioids but rather, embrace them. They are confident in what they are doing and gain a great deal of satisfaction from it.
2. **Willing Participant:** These are the PCPs who probably more closely align with the mindset of the Pain Specialists than their less-willing PCP colleagues. They don't claim to know everything about this topic but they are willing to take chances and find things out. These docs rise to the challenge of treating particularly difficult patients. They watch the Pain Specialists carefully and learn from them.
3. **Reluctant Observer:** This doc isn't closed-minded but rather uninitiated. This doctor has to be pulled in but he can be moved. This doc is willing to have a conversation and is open to the possibility of thinking about BTP and opioids in a new way. This doc has a significant fear of opioids and Cephalon will have to work to get his attention.
4. **Rigid Cynic:** These docs are stuck in their thinking about BTP. They are likely to have a great deal of misinformation but aren't interested in anything that would resolve that. They are closed-minded and have an intense fear of opioids. Their overall approach to the entire topic is avoidance.

Disengaged Physician

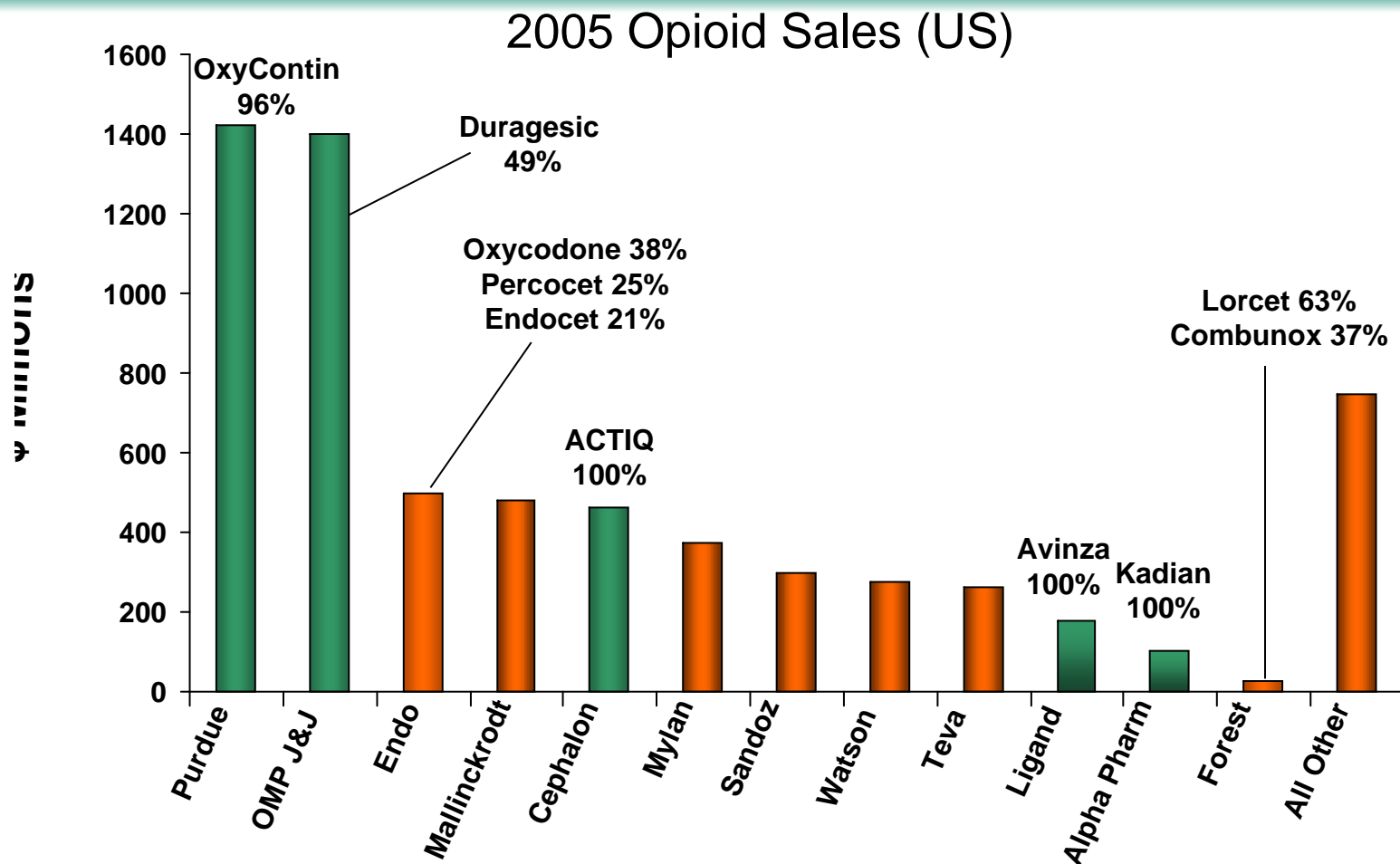
Patient Segment Name*	Characteristics
Helpless Sufferer	<ul style="list-style-type: none"> • Completely submit to the physical and psychological symptoms of pain • They are overwhelmed and incapacitated by their condition • Very routinized in their pill-taking behavior
Empowered Sufferer	<ul style="list-style-type: none"> • These patients rise to the challenge of pain • They aren't debilitated but face the issues head on • They emphasize the importance of a positive attitude and most exhibiting this response had a strong support system • Understand the pain cycle and the need to take BTP meds quickly to stop the pain before it climbs too high
Passive Sufferer	<ul style="list-style-type: none"> • In denial about their condition • Attitudes initially come across as acceptance but it is just a facade to help them ignore the pain
Angry Sufferer	<ul style="list-style-type: none"> • Extremely bitter about the state of their lives • Reflect a great deal on the past and the "what if's" and "why me's"
Restrained Sufferer	<ul style="list-style-type: none"> • They fear addiction, the future and how bad the pain will get • They place obstacles in front of themselves to fight for control • They push the envelope when it comes to taking their BTP medication and spend a great deal of time trying to make the decision whether to take it or wait

Topic	Physician *	Patient **
BTP terminology	If BTP is discussed physicians use “BTP” and “pain flares” interchangeably	Don’t use “BTP” instead describe pain as “uncontrolled” or use descriptive terminology (eg, flares, burning)
Quality of life	Treatment success reported by patient in terms of <ul style="list-style-type: none">• Work• Functioning	<ul style="list-style-type: none">• Focus on how pain has changed them as a person• Adapt lives based on pain• Wide range of coping characteristics **
Fear	<ul style="list-style-type: none">• Patient abuse of opioids• Patient diversion of opioids• Patients Psychological addiction (vs physical)• Regulatory scrutiny• Duped by patient for opioids	<ul style="list-style-type: none">• Addiction (loss of independence)• Over medication (sedated / confused)• Running out of opioids (rationing)• Anxiety over severity and timing of next BTP episode (unpredictability)• Physicians will stop prescribing opioids
Communication of pain	Distance themselves from chronic pain patients	Hold back communicating full impact of pain

* See physician segmentation ** see patient segmentation



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- The opioid market is changing significantly as OxyContin & Duragesic have recently lost exclusivity and ACTIQ will be going generic in 2006
- There will be a market leadership opportunity due to the lack of a dominant branded product



Majority of Sales Branded



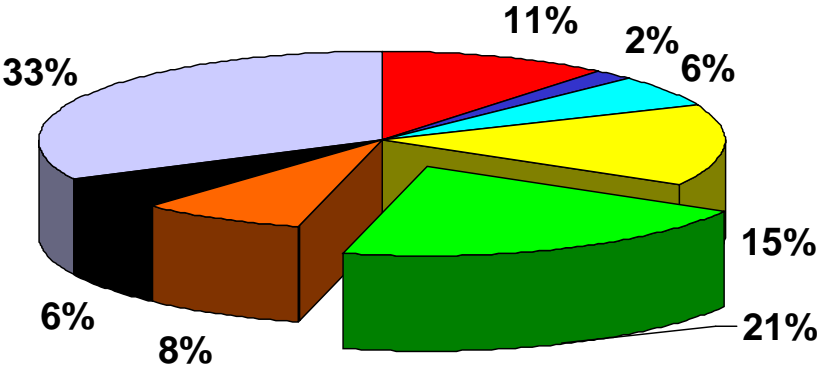
Majority of Sales Generic

Opioid Sales Calls (Q1 06)

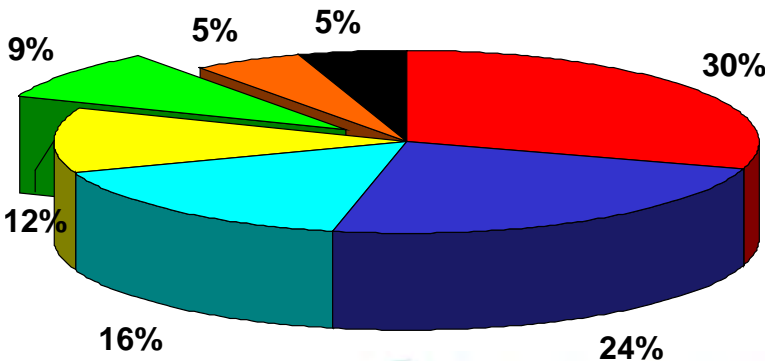
Rank	Pain	PCP
Depodur	1st	8th
ACTIQ	2nd	5th
Kadian	3rd	4th
Avinza	4th	1st
Duragesic	5th	6th
OxyContin	6th	3rd
Other	7th	7th
Combunox	8th	2nd

- ACTIQ has an aggressive market share in the Pain specialty (ranked 2nd) market segment
- ACTIQ has not fully penetrated the PCP market segment (ranked 5th)

Pain Specialists



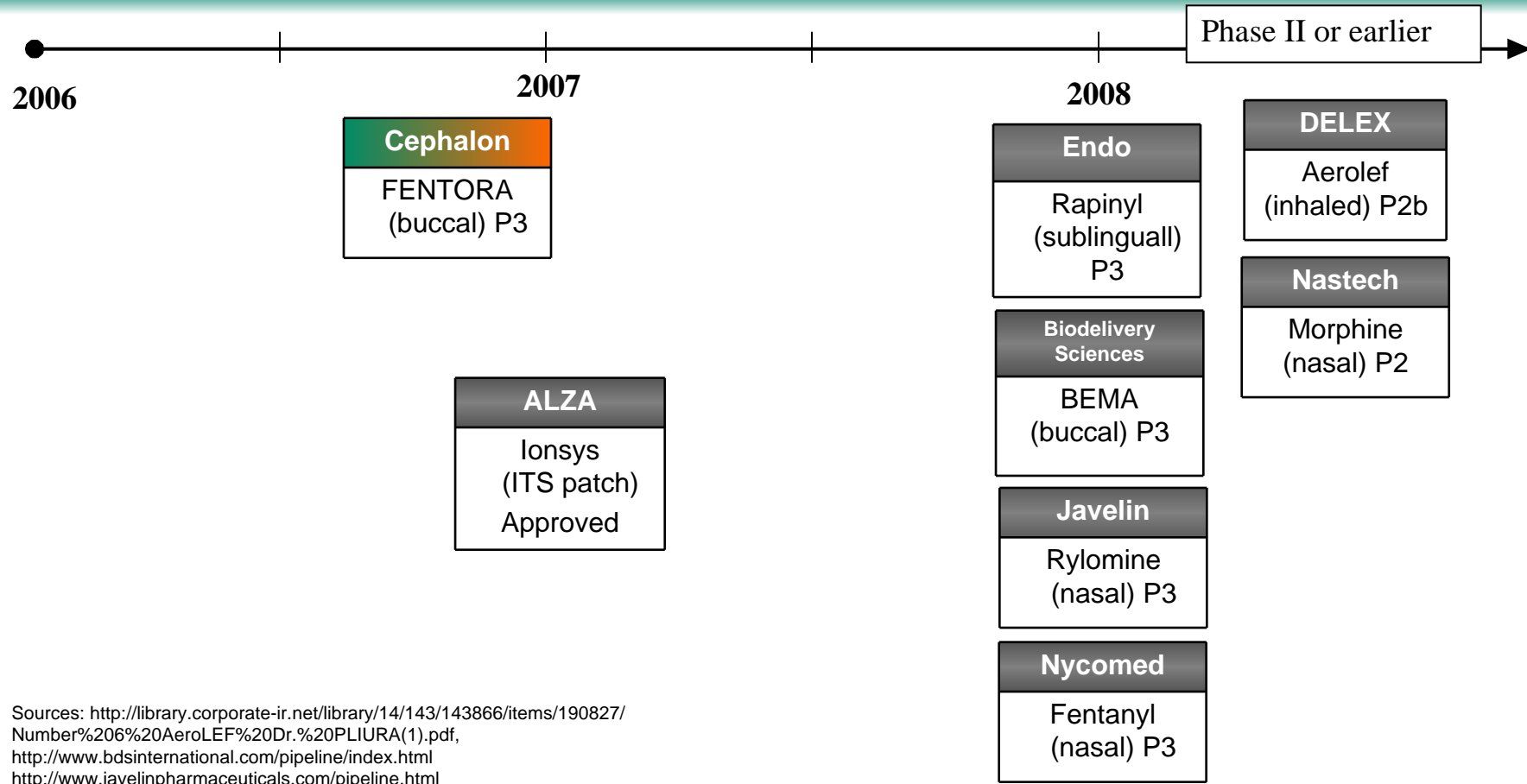
Primary Care



	2005 Pain Sales (US)	Primary Focus	Marketed Pain Products	Potential to Lead In Future
Purdue	\$1.4B	Pain Care	OxyContin (\$1.36B), MS Contin (\$32M), Pallodone (\$20M), OxyIR (818K)	Reputation suffers due to OxyContin issues and Palladone withdrawal
J&J	\$1.4B	Primary Care	Duragesic (\$687M), Tylenol Extra Strength (\$175), Ultracet (\$145M), Ultram (\$37M), Ultram ER*	Part of corporate strategy is to re-focus efforts in pain, developing new business unit
Endo	\$1.2B	Pain Care	Lidoderm (\$573M), Percocet (\$122M), Oxycodone ER (\$188M), Endocet (\$106M), Frova (\$47M), Morphine (\$70M), Opana Family	Potential to lead in the future due to single focus in Pain Category
Ligand	\$179M	Oncology, Pain Care	Avinza (\$179)	Strong presence in LAO market with no pipeline activity
Forest	\$32M	Pain Care, Cardio, CNS, Endo, OB-GYN	Lorcet (\$10M) Combunox (\$9.6M)	Not focused on Pain Category. CNS and CV are priorities.

Company	Phase II	Phase III	Pre-Reg/Reg
Alza (J&J)	Oxycodone (phase unknown)		Fentanyl Iontophoretic (Ionsys)- Approved 5-2006 Hydromorphone Oros
Endo	Lidoderm (chronic LBP) LidoPAIN (acute LBP) Chronogesic(Chronic moderate to severe pain) Ketoprofen patch Hydrocodone/paracetamol/dextromethorphan Oxycodone/dextromethorphan Oxycodone/paracetamol/dextromethorphan Sublingual fentanyl – Orexo Sufentanil - DURECT	Frova (menstrual migraine) Morphine/dextromethorphan Rapinyl (BTP in cancer patients)	
Forest	Memantine Neramexane RGH-896	Milnacipran	
OM Pricara	See Alza for J&J activity in pain management		
Ligand	No activity within pain management		
Purdue	“Several” Shionogi compounds (phase unknown) Note Purdue is privately held and provides limited disclosure		Tramadol XR agreement with King

Sources: Adis Data Information, www.endo.com/investor/profile.html, www.frx.com/research/pipeline.aspx, <http://www.ligand.com/products/pipeline.htm>, http://www.jnj.com/news/jnj_news/pdf/pi0601r9u7k4d4.pdf, <http://www.purduepharma.com/pressroom/news/20060110.htm>



Sources: [http://library.corporate-ir.net/library/14/143/143866/items/190827/Number%206%20AeroLEF%20Dr.%20PLIURA\(1\).pdf](http://library.corporate-ir.net/library/14/143/143866/items/190827/Number%206%20AeroLEF%20Dr.%20PLIURA(1).pdf),
<http://www.bdsinternational.com/pipeline/index.html>
<http://www.javelinpharmaceuticals.com/pipeline.html>
<http://www.nycomed.com/en/Menu/Investors/Pipeline/Pipeline.htm>

Competitor Vulnerabilities	FENTORA Basis for Differentiation
ALZA (Ionsys) – Limited indication (post-op) Endo (Rapinyll) – Delivery system – sublingual	ALZA (Ionsys)– Office vs Hospital Endo (Rapinyll)– OraVescent Technology

* 30 minute onset of action. Not a ROO

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Key Factors**Current Dynamics*****Economic***

- Unfavorable reimbursement environment
- Payers are increasing restrictions to drive usage to less costly drugs
- Payers don't understand BTP

Social/Cultural

- Abuse and diversion are top-of-mind topics for physicians and other stakeholders
- Society (including many physicians) are critical of their patients' inability to cope with their pain
- Pain patients feel misunderstood by physicians, friends, and family and often become frustrated and depressed
- Patients are often looking for an easy short-term solution to their pain and are not focused on long-term wellness

Political/Governmental

- Opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids
- FDA is hypersensitive about safety issues in a post-Cox II and OxyContin world

Legal

- DEA guidelines for writing opioids are unclear
- Ongoing issues between the DEA and various pain societies
- More physicians getting sued/licenses taken away

Clinical/Technological

- Lack of significant practical advancements in pain medicine
- New drugs, routes of administration, and improved control of side effects
- New insights into the anatomy and physiology of pain perception
- Greater understanding of how to integrate pharmacotherapeutic, psychological, and behavioral pain management approaches
- New tracking technology for packaging to avoid diversion

Growth Drivers

- Aging baby boomers and growing US population will increase the size of the chronic pain patient population
- Increase in treatment of chronic pain with opioids
- Pain Specialists are more aggressive in treating chronic pain
- More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume
- Increasing understanding about the proper identification, diagnosis and treatment of BTP
- New competitive entries

Growth Inhibitors

- Scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids
- Due to the widespread availability of generics in the opioid market, managed care has placed significant restrictions on the use of branded opioids
- Chronic pain practice standards (especially for BTP) are still evolving
- Physicians believe that increasing the dose or dosing frequency of LAOs can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by Purdue and Janssen]
- Perception by some physicians that SAOs are a preferred treatment option for BTP based on availability, ease-of-use, and cost

- The chronic pain market remains an attractive therapeutic area to invest in because of its substantial size and forecasted growth (\$10 billion – 2004 vs \$15.6 billion – 2014)
 - Acute pain and postoperative pain are additional areas for consideration
- Opioid market volume continues to grow mainly due to the aging population and increased usage outside of cancer pain
 - Pure SAOs – highest growth rate (TRx +21%, \$ +23%)
 - Combination SAOs – dominate volume (83% TRx market share)
 - LAOs – dominate market value (68% \$ market share)
- Generic expirations of blockbuster brands (ie, Duragesic, OxyContin) has resulted in a promotional void in the pain market
- Innovative drug delivery technology is the foundation of recent successful brands and drugs in the later stage of development

- BTP remains an untapped market
 - Physicians rely heavily on LAOs when addressing patients' BTP
 - Physicians also utilize generic SAOs due to availability, ease of use and cost
 - Even among high-users of ACTIQ, SAOs remain the treatment standard for BTP
- For the treatment of BTP, a communication gap exists between physicians and patients
- Concerns over opioid misuse and reimbursement hurdles continue to be key barriers to success
- The pain specialist continues to be the key market segment for new brand adoption
- Several new formulations of ROOs are in development and should come to market over the next 1-5 years helping to solidify this emerging sub-class of opioids

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Pain Franchise Commercial Vision

Cephalon is a leader in pain management

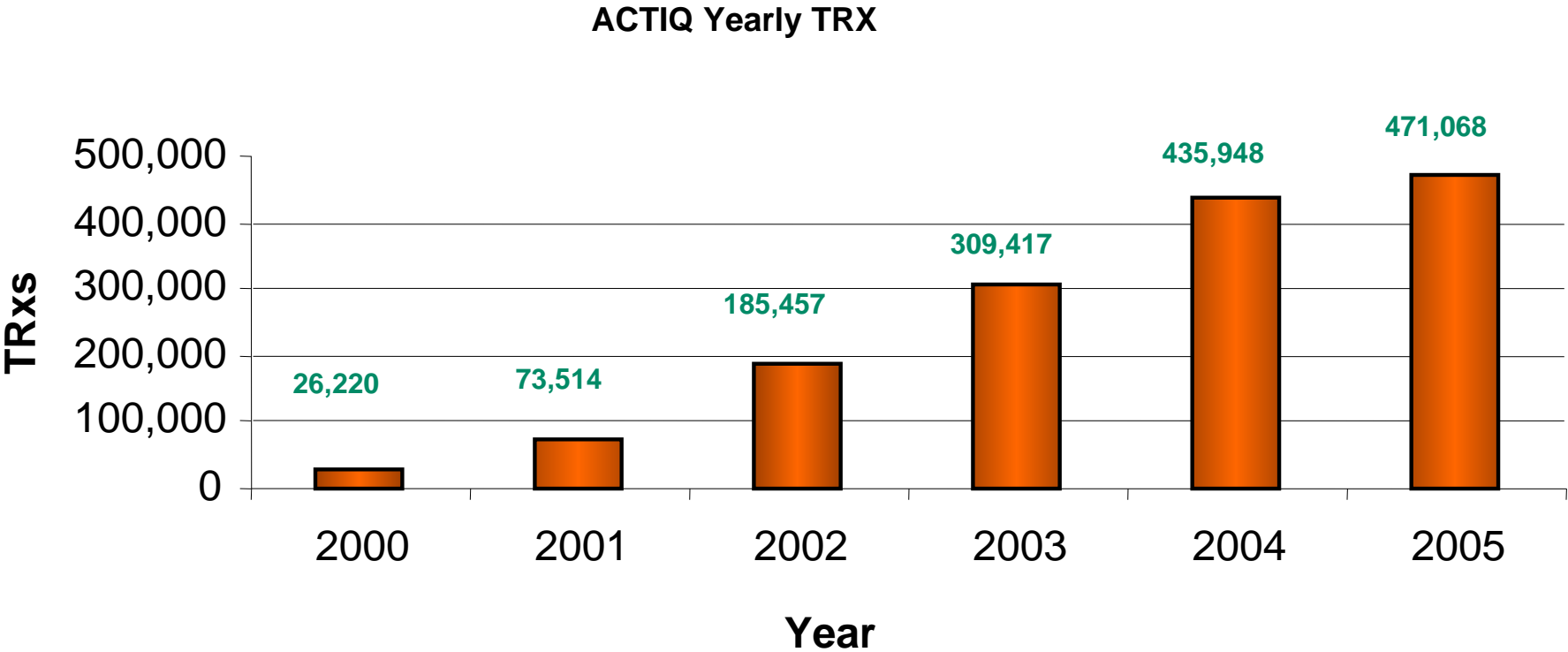
This vision will be achieved through:

- Applying breakthrough technologies
- Delivering innovative treatments
- Advancing understanding through comprehensive educational programs
- Providing support services for patients and healthcare providers
- Fostering relationships with key opinion leaders and professional societies

	Gap	Implications (Financial, Customers, Competitors)	Actions Required	Investment Needed
Present 2006	Time lag between ACTIQ LOE and FENTORA launch	•Generic OTFC entrants will have negative financial impact	•Focus on Fentora training •Enhance BTP educational efforts	
1-2 years (2007-2008)	Limited product portfolio beyond ACTIQ and FENTORA	•Field sales force not as efficient with one product in bag	•Intensify business development activities to identify and acquire additional products	• Acquire drug or co. \$50M - \$500M •BTP Campaign \$2-5 M
	Current pain salesforce size	•Limited reach only to highest potential physicians	•Identify field resources to expand reach	•\$10M - \$20M to expand sales force (est. of 50-100 reps)
3-5 years (2009-2013)	Limited pain products in pipeline	•High risk in single product/limited portfolios • Questionable ability to lead in the future without subsequent products.	•Increase discovery initiatives to identify new product candidates •Intensify business development activities	• Acquire drug or co. \$50M - \$500M •BTP Campaign \$5-10 M



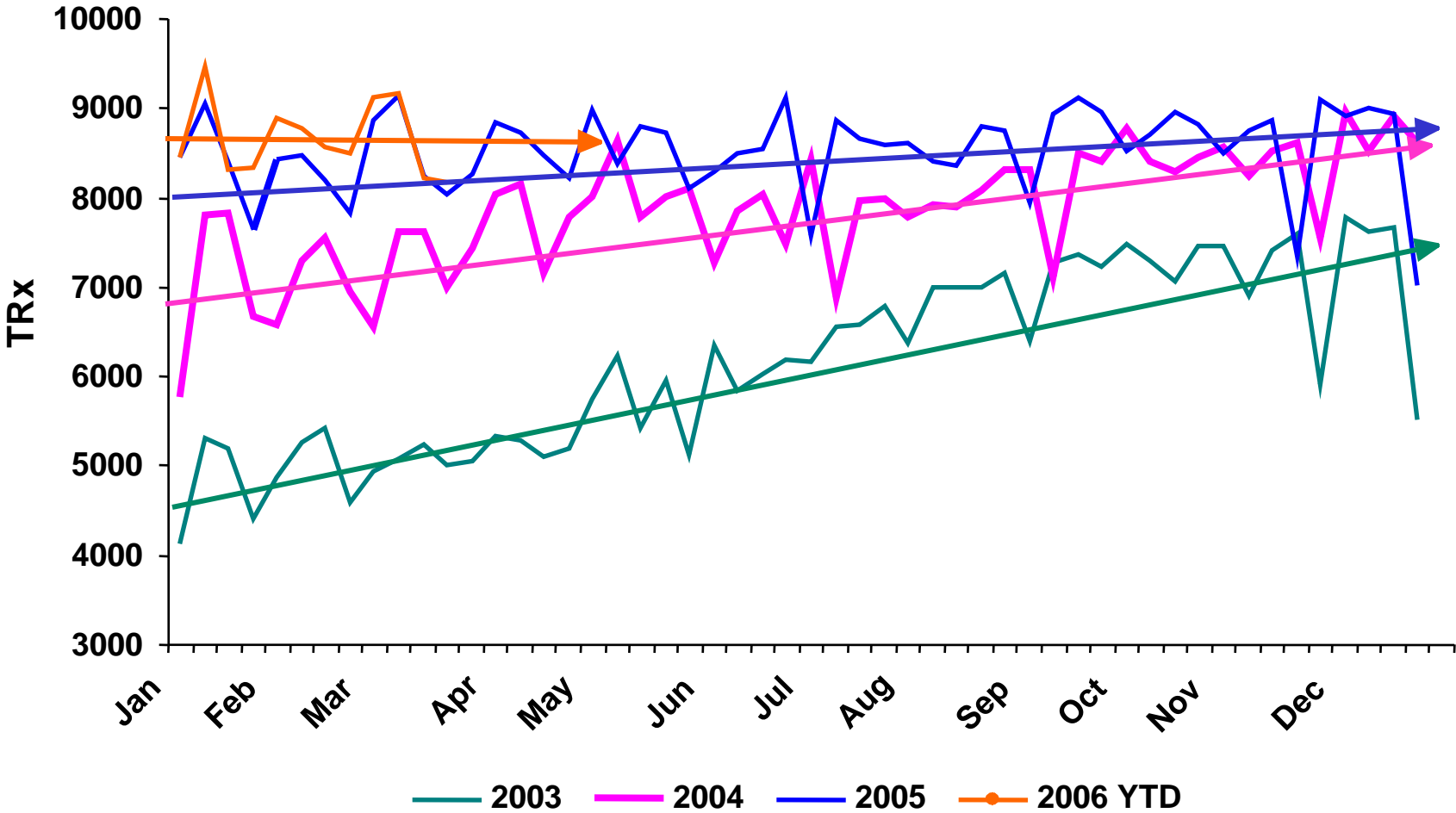
ACTIQ has had moderate success as a specialty product



Source: Cephalon

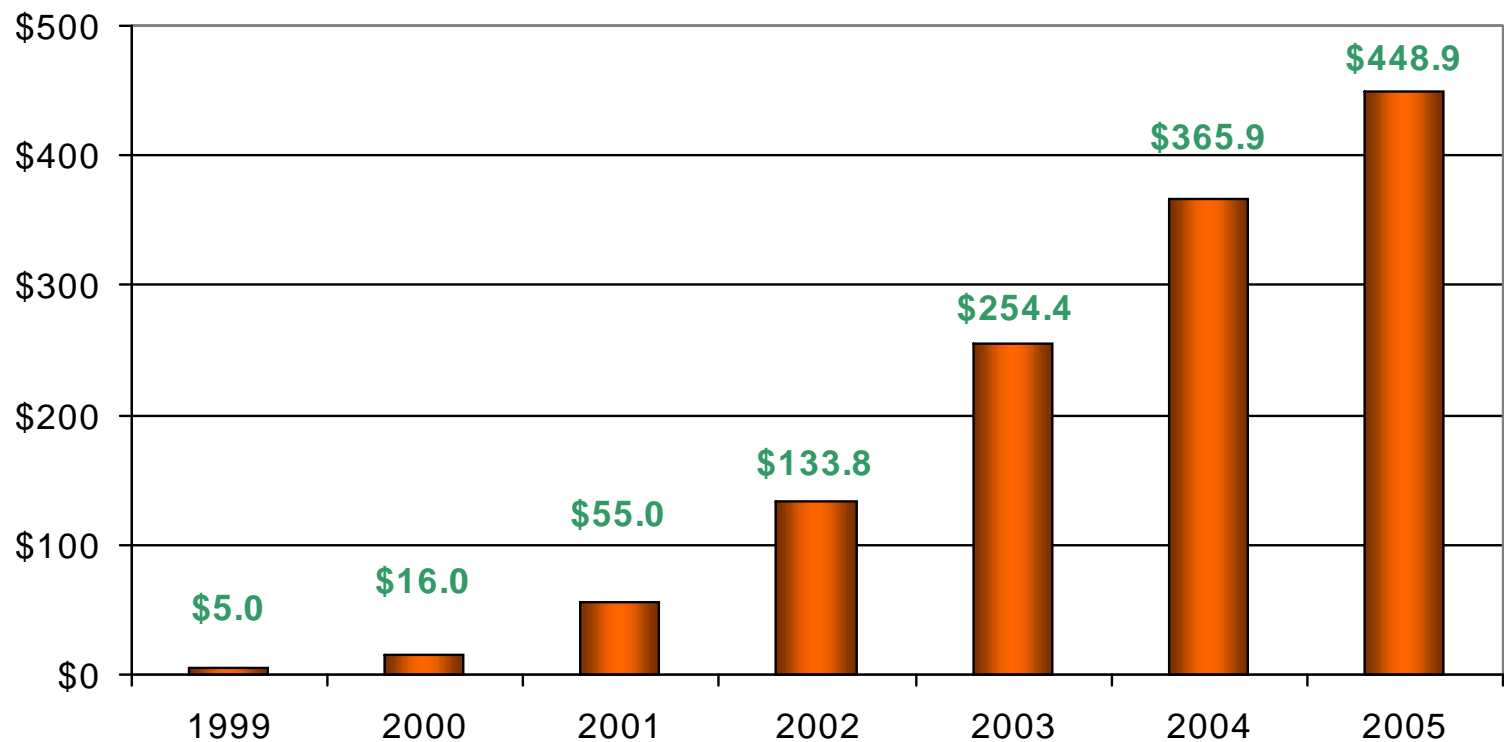


Recent trend is that scripts have remained relatively flat

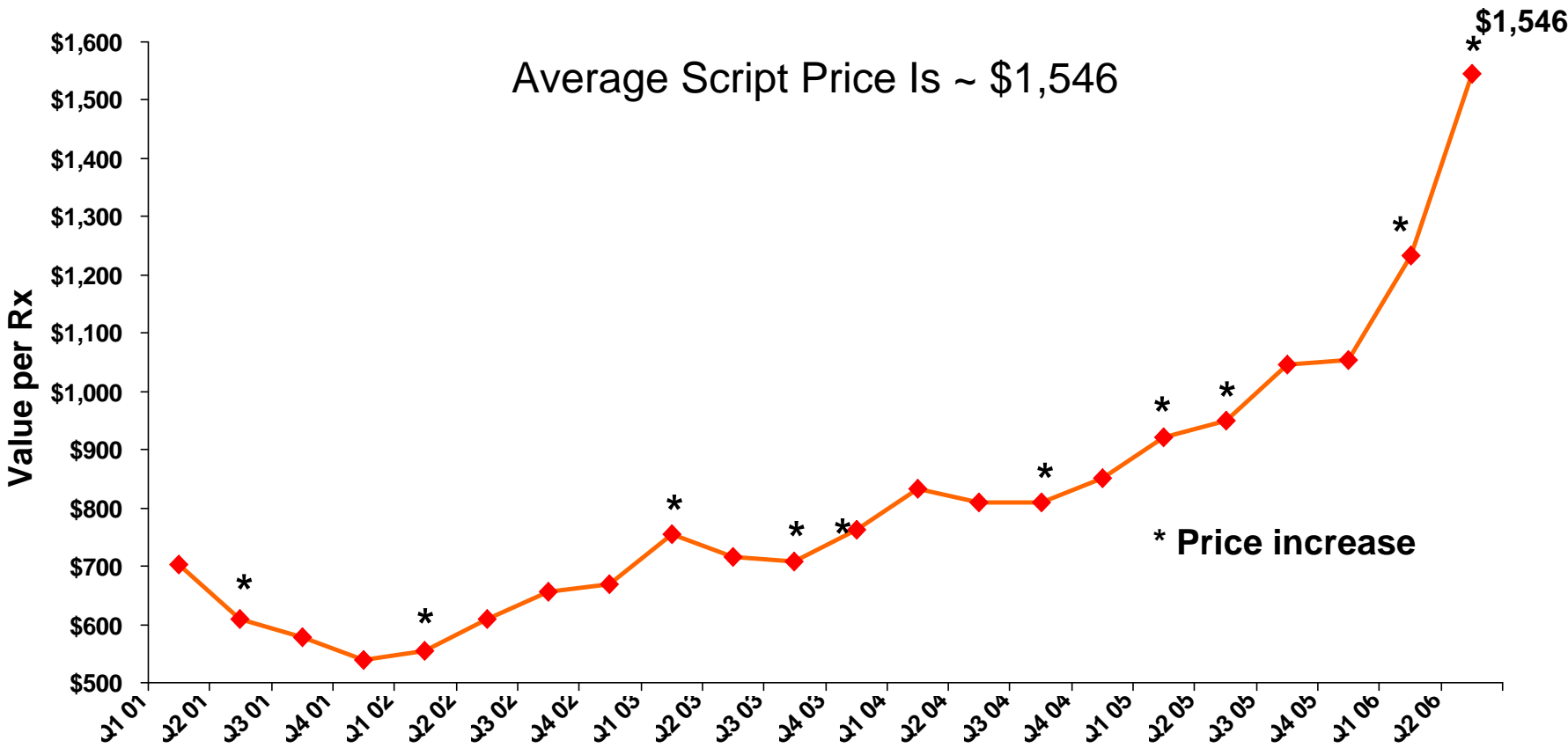


ACTIQ continues growth despite flat volume

ACTIQ Factory Sales
MM\$



Price increases have aided revenue growth

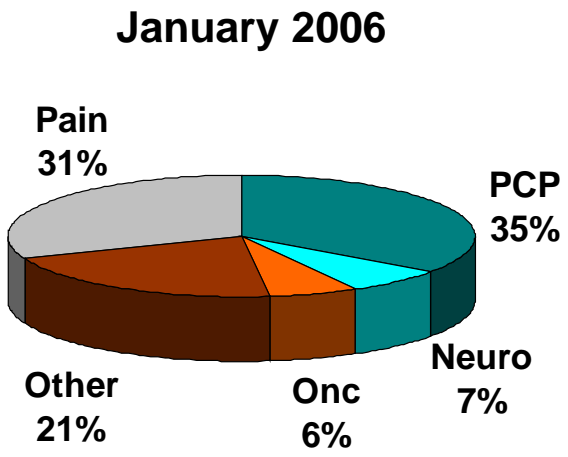
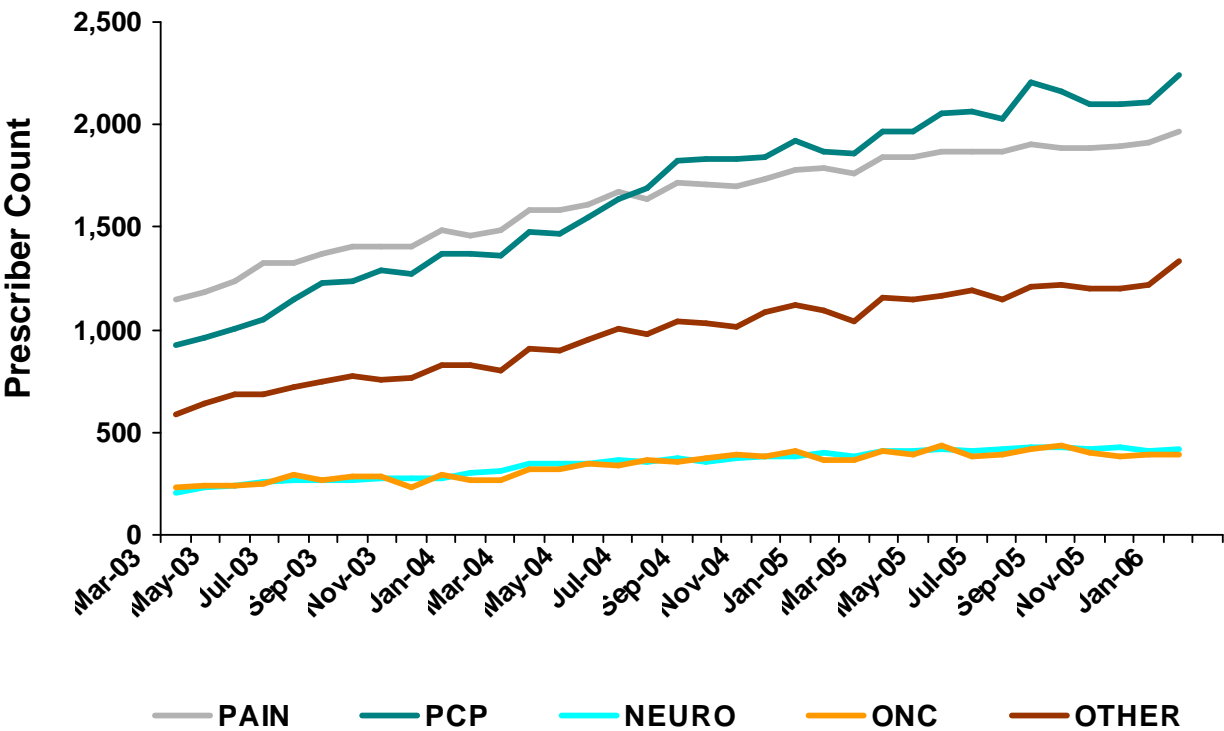


Source: IMS NPA Audit; Internal price as of January 31, 2006

*Time of price increase



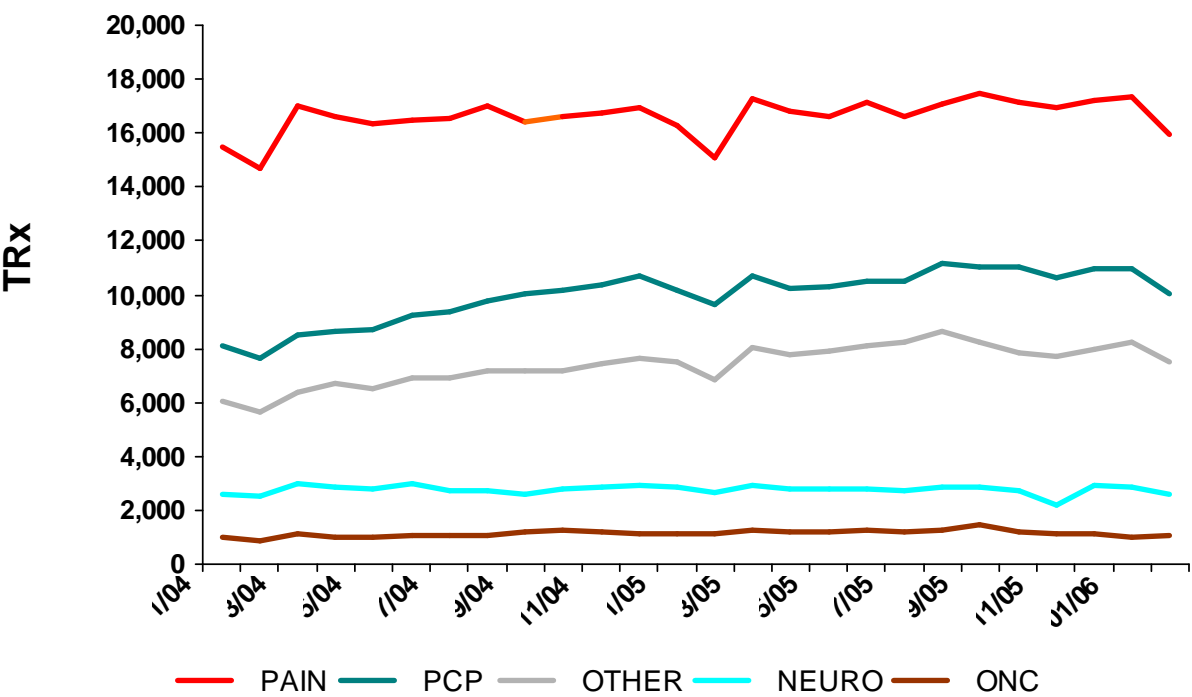
PCPs continue to outnumber Pain Specialists



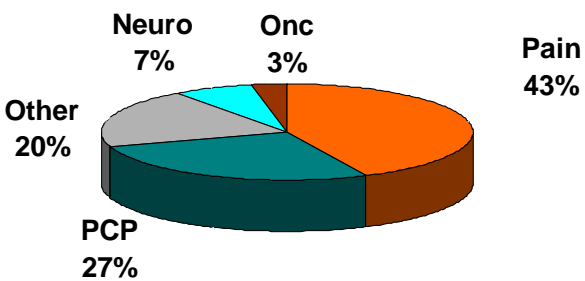
* Cephalon defined Specialty Group
Source: NDC



Pain specialists continue to write majority of prescriptions



February 2006



* Cephalon defined Specialty Group
Source: IMS NPA




- Pain Overview
- Market Assessment
 - Market Analysis
 - Customer Analysis
 - Competitive Analysis
 - Environmental Trends
- Franchise Assessment
- **Product Overview**
- SWOT Analysis
- Strategy Formation
- Critical Success Factors
- Key Messages
- Implementation
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- FENTORA is fentanyl delivered via OraVescent® Technology
- OraVescent Technology
 - Utilizes effervescence in a buccal tablet
 - Improves rate and extent of drug absorption
 - Minimizes first-pass metabolism
- Effervescence reaction acts as absorption enhancer by accomplishing the following:
 - Dynamic pH shifts that enhance dissolution and optimize the speed and extent of drug absorption
 - May reduce thickness of the mucosa layer
 - May open tight junctions

Attributes		FENTORA	ACTIQ
Indication		Launch: BTP in patients w/ Ca 2008: BTP in non-Ca patients	BTCP
Efficacy	Onset	15 min (99-14) < 15 min, + “meaningful relief” (3039)	15 min
	Duration	60 min (99-14) 120 min measurement (3039)	60 min
PK (FENTORA 400 mcg vs ACTIQ 800 mcg)	Absolute Bioavailability	65%	47%
	Transmucosal Absorption	48%	22%
	Cmax (mean ng/mL)	1.02	1.26
	Tmax (median, min)	46.8	90.8
Administration	Convenience	Discreet tablet	Large lozenge on a stick
	Ease of Use	Passive administration	Active administration
	Dosage	Launch: 100, 200, 400, 600, 800 mcg LCM: 300, 1000, 1200 mcg	200, 400, 600, 800, 1200, 1600 mcg
	Titration	Multiple 100 tablets up to 400 mcg, then 1 higher strength at a time	1 higher strength at a time

Attributes		FENTORA	ACTIQ
Safety	AE Profile 	Comparable to other opioids	Comparable to other opioids
	Abuse Potential	Comparable to other opioids	Comparable to other opioids
	Accidental Exposure	Comparable to other opioids	Lozenge on stick presents potential concerns: <ul style="list-style-type: none"> – Pediatric exposure – Partially used unit exposure
Formulation		Sugar-free	Sugar

Features/Benefits	FENTORA	ACTIQ	SAOs
Efficacy – Onset	+++	++	-
Efficacy – Duration	++	++	+
Convenience	++	+	++
Ease of Use	+	-	++
Ease of Titration	+	-	++
Side Effect Profile	+	+	+
Abuse Potential	-	-	-

Physician Perception of FENTORA

Drivers	Barriers
<ul style="list-style-type: none"> • Faster onset of pain relief • Overall efficacy • Convenient administration • Ease of use (vs IV administration) • Sugar-free • Unique delivery system • Utilizes less fentanyl • Discreet (ie, no handle vs ACTIQ) 	<ul style="list-style-type: none"> • Anticipated high cost <ul style="list-style-type: none"> – Hassle associated with coverage • Potential for abuse • Potent opioid <ul style="list-style-type: none"> – Reserve fentanyl refractory patients • No handle administration <ul style="list-style-type: none"> – ACTIQ saves \$ with partial dosing – ACTIQ can be removed if S/Es

- Overwhelmingly, the majority of physicians expressed an interest in this product and felt it had a place in their practice



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Strengths

- Onset of analgesia vs placebo <15 minutes
- Duration of analgesia measured up to 120 minutes
- Discreet and convenient dosing formulation
- Predictable bioavailability vs ACTIQ
- Efficient drug delivery (65% absolute bioavailability)
- Easier dose titration scheme than ACTIQ
- Data on ACTIQ to FENTORA switch
- Clinical program to expand label
- Patent on FENTORA through 2019

Threats

- Limited understanding of BTP and its appropriate management outside a small community of pain specialists
- Fear of abuse and diversion with opioids
- Increasing government restrictions on C-II opioids
- Generic SAOs and most importantly a generic OTFC prior to launch
- Published data for ACTIQ vs IV morphine documenting median time for pain relief 4.2 minutes
- Diverse prescriber audience
- Managed care and other third-party payers (including Medicare Part D and Medicaid) increasing their efforts to restrict high-cost drug use
- Competitive pricing pressure
- Noninclusion of FENTORA in treatment guidelines
- Emerging ROO pain formulations (eg, Rapinyll)

Weaknesses

- C-II abuse and diversion potential
- Efficacy data do not differentiate FENTORA from ACTIQ
- Cost vs other SAOs (branded and generic alternative therapeutic options)
- Limited label (BTP in cancer patients) at launch and potentially up to 3 years postlaunch due to carcinogenicity study
- Perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs mcg)
- Predicted reimbursement restrictions
- Cephalon not a lead player in pain market

Opportunities

- KOL eagerness to evaluate and establish standards for treatment guidelines for BTP
- Increased focus on pain management from JCAHO (5th vital sign) and NIH (Decade of pain Control and Research)
- Though limited there is some increasing awareness and understanding of BTP
- Concentrated ACTIQ prescriber base enables for focused targeting
- Limited number of promoted products within the market segment Aging population
- Opportunity to develop HEOR data for BTP (burden of illness)

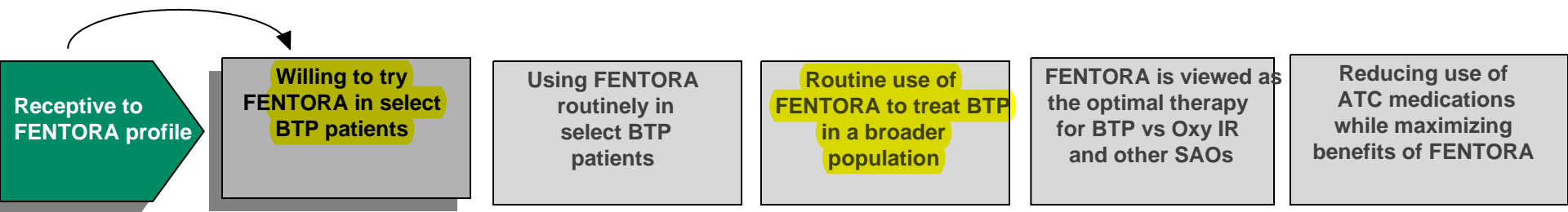


- Pain Overview
- Market Assessment
 - Market Analysis
 - Customer Analysis
 - Competitive Analysis
 - Environmental Trends
- Franchise Assessment
- Product Overview
- SWOT Analysis
- **Strategy Formation**
- Critical Success Factors
- Key Messages
- Implementation
- Tactical Plan
- Results Required
- Control and Monitoring



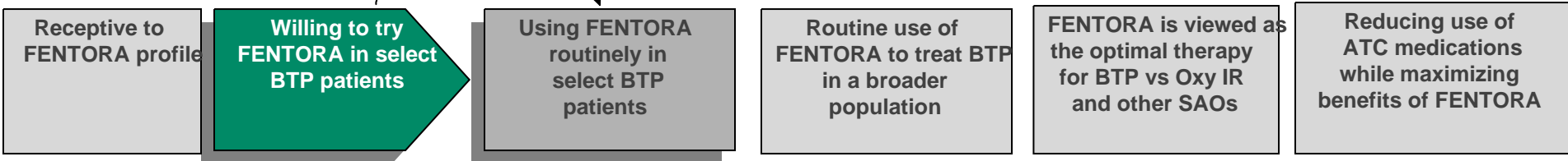
What We Should Be: The optimal solution for BTP
Brand Essence: Effervescent speed

Differentiate from existing options



What We Should Be: The optimal solution for BTP
Brand Essence: Effervescent speed

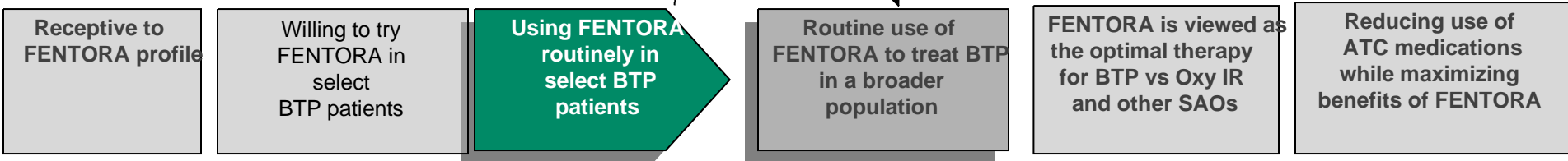
Reinforce and promote routine use



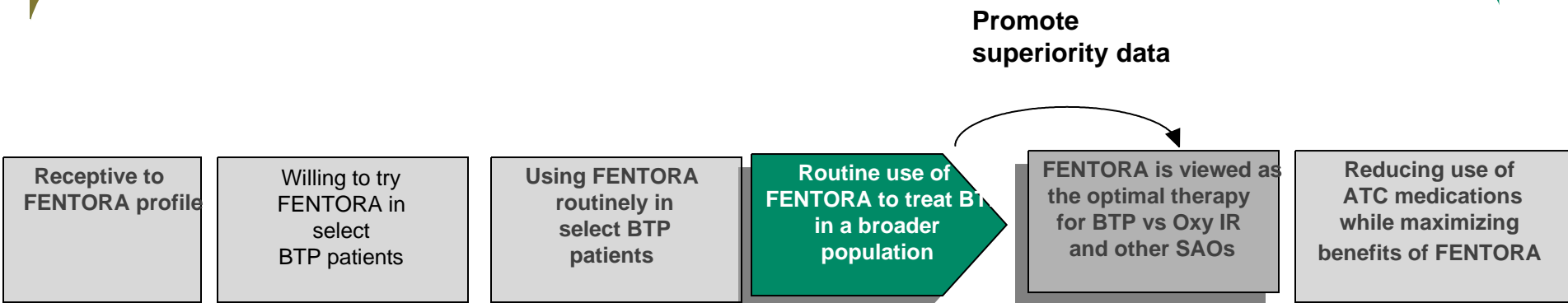
What We Should Be: The optimal solution for BTP
Brand Essence: Effervescent speed



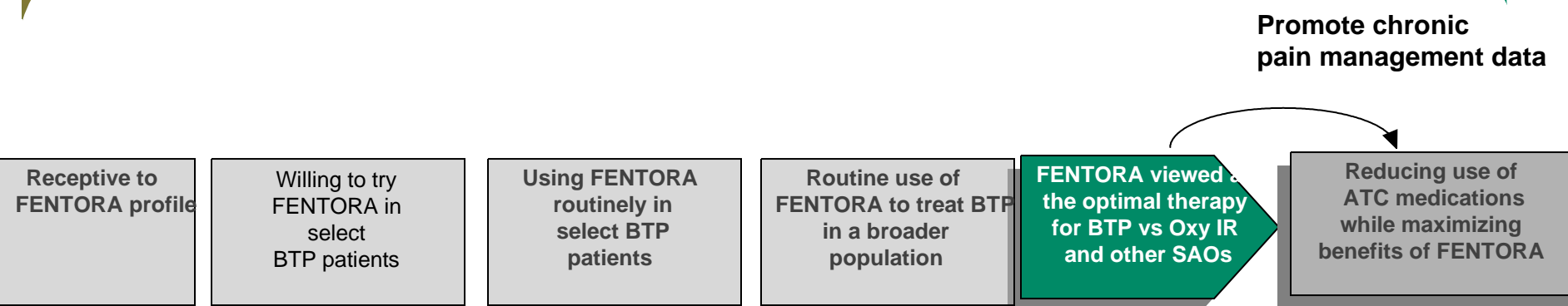
Promote
noncancer data



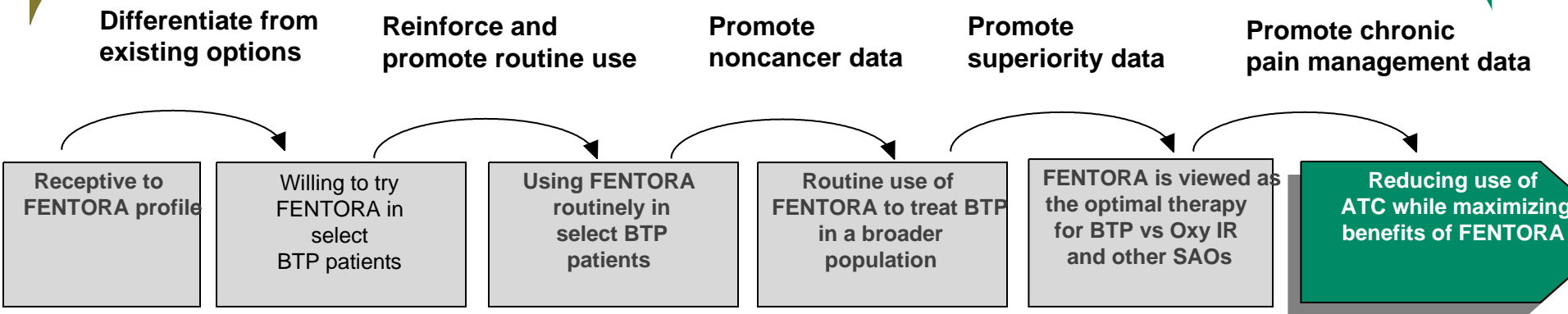
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What We Should Be: The optimal solution for BTP
Brand Essence: Effervescent speed



What We Should Be: The optimal solution for BTP
Brand Essence: Effervescent speed



FENTORA Positioning

FENTORA is the first and only fentanyl buccal tablet that utilizes an effervescence reaction to provide the most rapid onset of analgesia of any oral opioid resulting in improved patient functioning and activities of daily living.



Cancer BTP

NDA filed with 99-14, 99-15, 1026, 1027, 1028, 1029

Cancer BTP-Differentiation

File sNDA for additional claims with 3039

Non-Cancer BTP

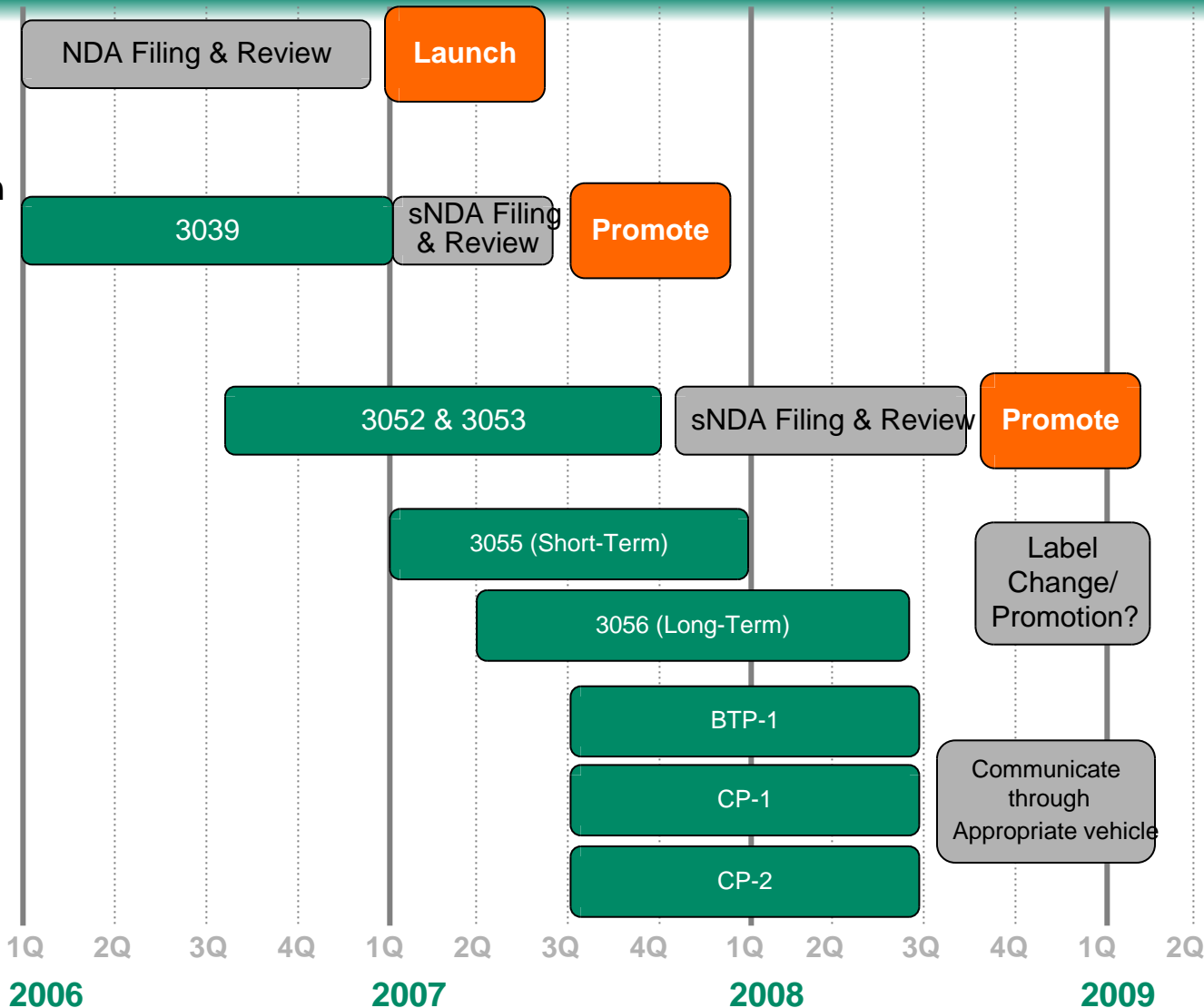
File sNDA for Non-Cancer New Indication with 3040, 3041, 3042, 3052, 3053

HTH BTP

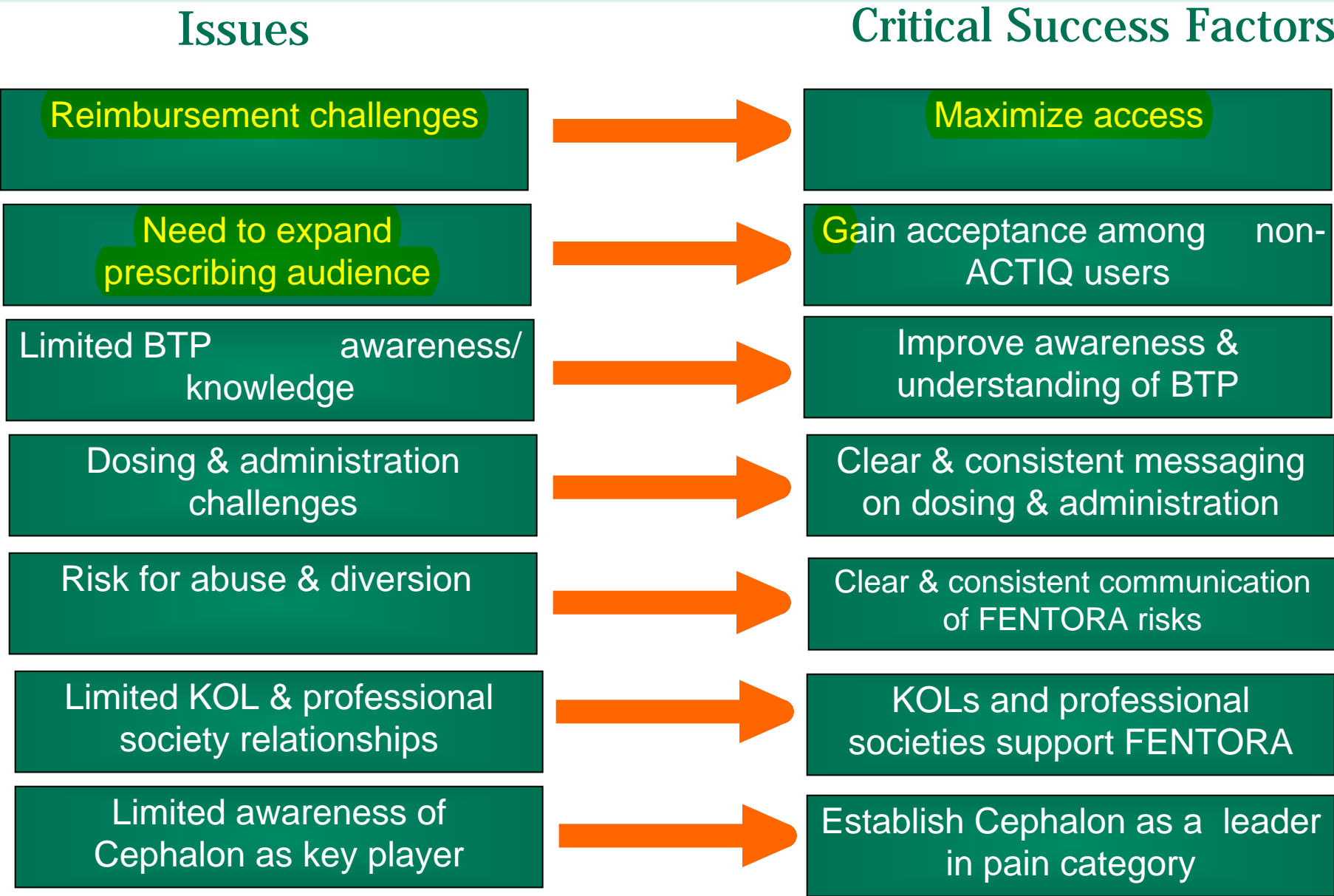
Establish HTH Superiority for Non-Cancer BTP

Chronic Pain

- a) Optimize BTP/Decrease ATC
- b) Switch from SAOs
- c) Switch from LAOs



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 - Implementation
 - Tactical Plan
 - Results Required
 - Control and Monitoring



- Pain Overview
- Market Assessment
 - Market Analysis
 - Customer Analysis
 - Competitive Analysis
 - Environmental Trends
- Franchise Assessment
- Product Overview
- SWOT Analysis
- Strategy Formation
- Critical Success Factors
- **Key Messages**
- Implementation
- Tactical Plan
- Results Required
- Control and Monitoring

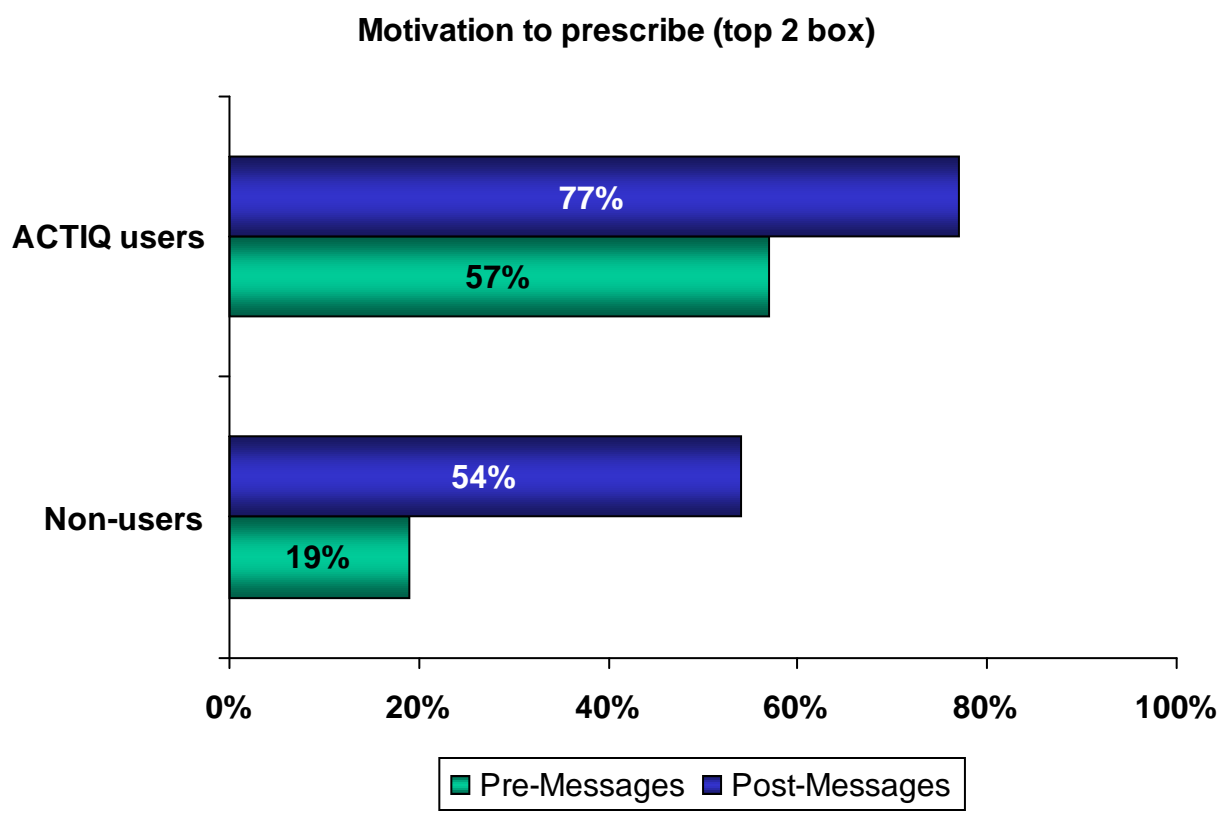


Core Messages *

- The sudden strike of BTP may require a rapid-onset opioid
- FENTORA is a rapid-onset opioid
 - Onset of pain relief in as little as 10 minutes
 - Duration of relief demonstrated for up to 120 minutes
- OraVescent® drug delivery technology utilizes effervescence for optimized delivery of fentanyl across the buccal mucosa
- Convenient, discreet, and sugar-free

*Messaging draft – pending research results and DDMAC approval

Physicians react positively to messages



* To what degree does this new information motivate you to prescribe FENTORA over other short-acting opioid (SAO) medications for breakthrough pain (1-7 scale)?

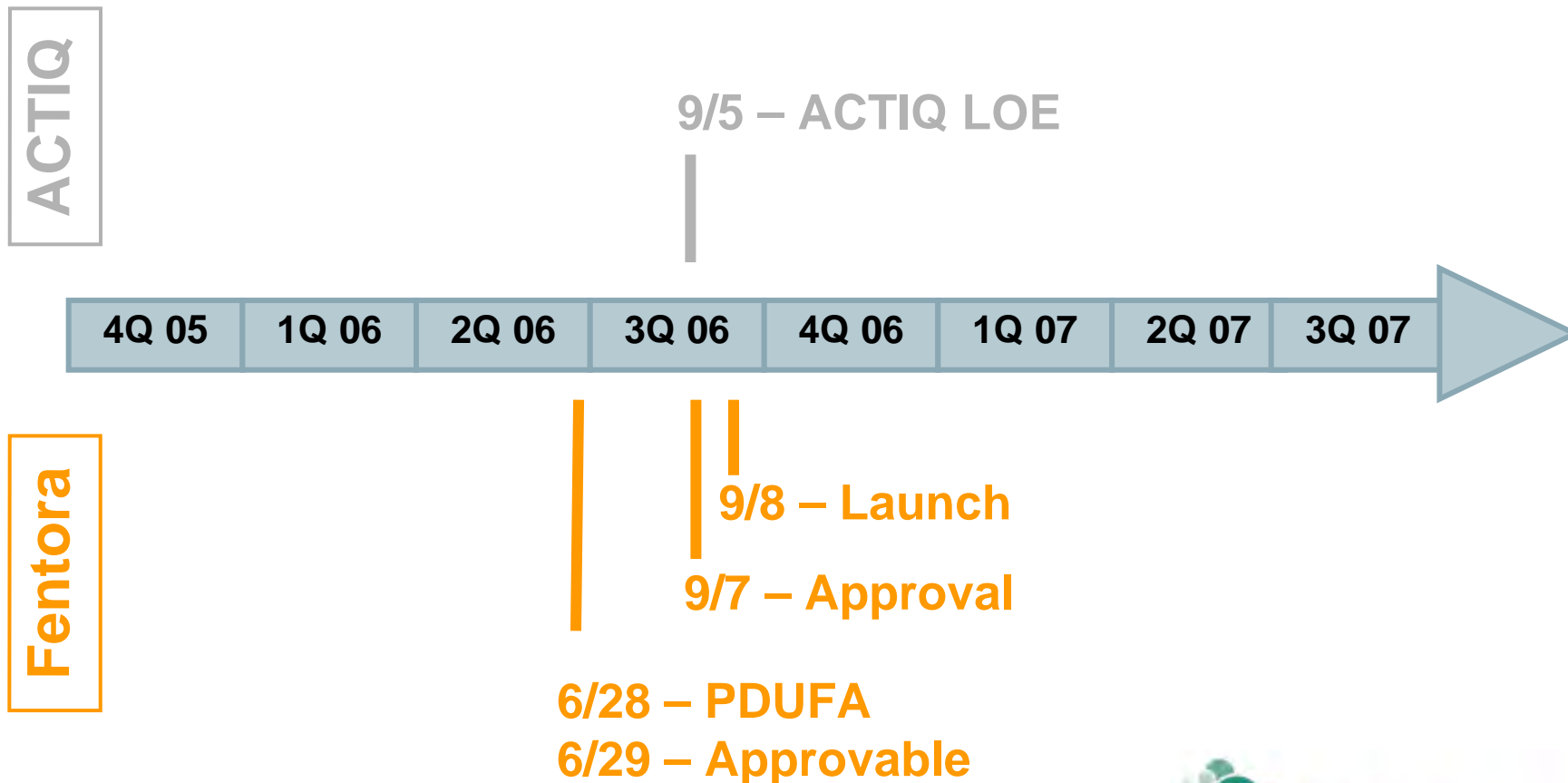
Source: Gfk V2 Q2 06 N = 77 (users) N = 52 (non-users)



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Current Working Assumptions



Issue

Anticipated reimbursement challenges

Critical Success Factor

Ensure that physicians/patients have access to FENTORA

Strategies

- Aggressively implement a comprehensive and targeted managed care plan
- Partner with managed care organizations to demonstrate the utility of FENTORA within their systems
- Promote Cephalon's commitment to risk minimization to managed care and pharmacists
- Actively communicate the benefits of FENTORA with pharmacy directors
- Establish ROO sub-class to further differentiate from SAOs

Issue

Need to expand prescribing audience beyond ACTIQ users

Critical Success Factor

Continue to differentiate FENTORA from other BTP treatments in an effort to gain acceptance of FENTORA among non ACTIQ users

Strategies

- Target slow adopting ACTIQ users with focused messages
- Continue to create high awareness among targeted physicians
- Leverage new additional and patient preference claims from 3040 data and other clinical initiatives
- Actively disseminate clinical data and publications through appropriate means
- Continue to establish and differentiate ROOs from SAOs to demonstrate a valuable proposition

Issue

Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP

Critical Success Factor

Improve BTP awareness and understanding among physicians and patients

Strategies

- Expand BTP market by increasing physician and patient awareness of BTP
- Continue to establish BTP as a distinct clinical problem in need of independent assessment and targeted treatment
- Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP
- Support BTP educational initiatives

Issue

Anticipated dosing and administration challenges for both physicians and patients

Critical Success Factor

Maintain clear and consistent messaging on the proper dosing and administration of FENTORA

Strategies

- Communicate and disseminate appropriate educational materials related to delivery and administration
- Educate physicians and patients on how the delivery system is different from traditional oral administration
- Communicate clinical benefits of titration and maintenance dosing

Issue

Risk for abuse, addiction, and diversion

Critical Success Factor

Maintain clear and consistent communication of FENTORA risks to all key stakeholders

Strategies

- Educate HCPs on appropriate patient selection
- Educate patients about safe use of FENTORA and allay fears of opioids
- Communicate and disseminate appropriate educational materials related to risk minimization
- Promote Cephalon's commitment to risk minimization to all HCPs
- Continue to implement risk minimization tools

Issue

Limited KOL and professional society relationships

Critical Success Factor

KOLs support FENTORA as an effective treatment option for BTP

Strategies

- Improve and expand KOL relationships
- Continue to consult KOLs to better inform Cephalon on the optimal design of FENTORA clinical studies

Issue

Limited awareness of Cephalon as key player in the pain care market

Critical Success Factor

Establish Cephalon as a leader in the pain market

Strategies

- Continue to promote to Cephalon internal team the importance of developing a multi product pain franchise
- Promote Cephalon's dedication to advancing the science of pain therapy
- Identify product acquisition candidates for pain franchise
- Continue to demonstrate Cephalon's commitment to partner with KOLs to advance the field of pain management

Category	Amount
Marketing Budget	\$35 MM
Medical Education	\$10 MM
Publications	\$2 MM
Clinical (LCM)	\$25 MM



End of Phase 1 Market Assessment and Strategic Development

- LRP/ assumption review / approval (May 17) with management
- Situation review with management – approval of critical success factors/ core strategies- by end of June
- Tactical plan development - July/ early August
- Full marketing plan review with budgets - Aug
- Dissemination of Marketing plans to other departments- end Sept/ early Oct.